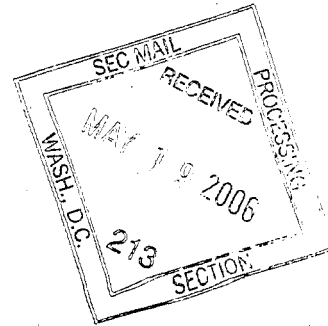




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Ortec International, Inc.

2005 ANNUAL REPORT

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Table of Contents

	Page
Letter to Shareholders	3
Information Relating to Forward Looking Statements	4
Description of Business	4
Market for Common Equity and Related Stockholder Matters	14
Management's Plan of Operation	15
Financial Statements	F1

MAJOR PORTIONS OF THIS ANNUAL REPORT ARE EXCERPTS FROM OUR ANNUAL REPORT ON FORM 10-KSB FOR THE YEAR ENDED DECEMBER 31, 2005, WHICH WE HAVE FILED WITH THE SECURITIES AND EXCHANGE COMMISSION. WE WILL PROVIDE A COPY OF THAT FORM 10-KSB, WITHOUT CHARGE, TO OUR SHAREHOLDERS UPON THEIR REQUEST. SUCH REQUEST SHOULD BE ADDRESSED TO:

Ortec International, Inc.
3960 Broadway
New York, New York 10032
Attn: Alan W. Schoenbart, CFO

Letter to Shareholders

Dear Shareholders,

2005 was a year filled with challenges, resiliency, and sustained progress. Mustering the fortitude to overcome the challenges that presented themselves, we now stand at a positive inflexion point. We look forward to the coming year with a sense of optimism based on the real value enhancing opportunities that lie ahead while ever mindful of the new challenges that inevitably are on the horizon.

Our near term value enhancing opportunity is obtaining approval for the use of OrCel® in the treatment of venous leg ulcers. Towards achieving that end, we have recently completed enrollment of a pivotal (Phase III) trial designed to confirm the superiority of OrCel® over the standard of care therapy in the healing of difficult to heal venous leg ulcers. Within the next few months, after the completion of the treatment phase of the trial, we look ahead to analyzing the data and being able to submit a Pre-Market Approval (PMA) application to the Food and Drug Administration (FDA) later this year. We continue to believe OrCel® is a first in class product which will be marketed to patients with significant unmet medical needs. Clearly, approval of our product by the FDA should be a value-enhancing event for our company.

In an attempt to further enhance shareholder value, broaden investor interest, and create additional value-enhancing opportunities, we recently acquired two fibrin derived advanced biomaterial technologies, Fibrin Microbeads (FMB) and Haptides™. FMB have the potential to play a significant role in advancing stem cell therapy having demonstrated the ability to efficiently recover adult stem cells and allow for differentiation, proliferation, and potential reimplantation into the patient. Haptides™ utilize proprietary synthetic peptides that mimic the mechanism of cell attachment to fibrin. These peptides have demonstrated the ability to significantly enhance cell attraction and attachment. We believe Haptides™ can be of significant value in the development of product opportunities applicable to tissue regeneration, cosmetic tissue augmentation, wound healing, and orthopedics. We are implementing a business strategy for these newly acquired technologies that involves in-house development and our seeking licensing and collaborations for a range of applications. Adding these cutting edge technologies to our existing product and technology portfolio puts us squarely in the very exciting and growing field of stem cells and regenerative medicine and provides us with a number of synergistic technologies with which we can develop products. We believe our expertise and knowledge in the areas of cell biology, biomaterials, and tissue regeneration which we have developed during the past 15 years, provide a solid platform from which we can effectively expand our focus to the development of stem cell and regenerative medicine products.

To allow us to achieve our objectives and realize the value associated with our accomplishments, we will need to continue to access the capital markets. During the past year, we managed to attract new investors and received equity capital in excess of \$11,500,000 and concurrent with the recent acquisition of our two new technologies, we raised an additional \$6.1 million. As we continue to make progress and implement our business plan, with the continued support of our shareholders, we believe we can continue to raise the capital that will be necessary to reap the fruits of our labor.

The success of a company is dependent on an array of factors, some which are controllable and those that are not. Together with our dedicated and valued employees, we continue to have the commitment and dedication to focus on those factors which we can control and maintain the confidence and demonstrated ability to react to those we cannot.

We thank you, our shareholders, old and new, for your continued support which is critical to achieve our goals and allow us to grow the value of our company.



Ron Lipstein
Vice Chairman and CEO

May 2006

INFORMATION RELATING TO FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-KSB includes forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934. These forward-looking statements involve a number of risks and uncertainties. Such forward-looking statements include statements about our strategies, intentions, expectations, goals, objectives, discoveries, collaborations, preclinical and clinical programs, and our future achievements. These forward-looking statements can generally be identified as such because the context of the statement will include words such as "may," "will," "intends," "plans," "believes," "anticipates," "expects," "estimates," "predicts," "potential," "continue," or "opportunity," the negative of these words or words of similar import. For such statements, we claim the protection of the Private Securities Litigation Reform Act of 1995. Readers of this Annual Report on Form 10-KSB are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date on which they are made. These forward-looking statements are based largely on our expectations and projections about future events and future trends affecting our business, and are subject to risks and uncertainties that could cause actual results to differ materially from those anticipated in the forward-looking statements. Important factors that could cause actual results to differ materially from those in these forward-looking statements are disclosed in this Annual Report on Form 10-KSB, including, without limitation, those discussions under "RISK FACTORS" in "Item 1. Business". In addition, past financial and/or operating performance is not necessarily a reliable indicator of future performance and you should not use our historical performance to anticipate results or future period trends. We can give no assurances that any of the events anticipated by the forward-looking statements will occur or, if any of them do, what impact they will have on our results of operations and financial condition. Except as required by law, we undertake no obligation to publicly revise our forward-looking statements to reflect events or circumstances that arise after the filing of this Form 10-KSB or documents incorporated by reference herein that include forward-looking statements.

In this Annual Report on Form 10-KSB, "Ortec," "we," "us" and "our" refer to Ortec International, Inc. and our wholly owned subsidiary, Orcel LLC, unless the context otherwise provides.

PART I

Item 1. DESCRIPTION OF BUSINESS

Overview

We are a development stage tissue engineering company with core competencies in cell culturing, biology and biomaterials. We have developed a proprietary and patented technology that we call OrCel ® (ORCEL), which is used to stimulate the repair and regeneration of human skin. ORCEL is a two-layered tissue engineered dressing that consists of human derived skin cells, both dermal and epidermal, supported within a porous collagen matrix. The composite matrix is seeded with keratinocytes (epidermal cells) and fibroblasts (dermal cells). When ORCEL is applied to the wound site, it produces a mix of growth factors that stimulates wound closure.

Our primary target patient populations for the use of ORCEL are persons with venous stasis and diabetic foot ulcers, which we believe are large potential markets for the use of ORCEL. We also believe that ORCEL may have applications for cosmetic surgery, and other types of chronic and acute wounds.

We have developed the technology for the cryopreservation of ORCEL without diminishing its effectiveness. Cryopreservation is the freezing of our product to give it an extended shelf life. Currently, ORCEL has a shelf life of no less than seven months, as opposed to only a few days with the non-cryopreserved product. We believe that the longer shelf life will reduce the cost per unit of producing ORCEL as well as provide us with a marketing advantage over non-frozen competitive products.

In 2001, the FDA granted our application for the commercial sale of the fresh form of ORCEL for the treatment of donor site wounds. A donor site wound is created in an area of the patient's body from which the patient's skin was taken to cover a wound at another part of such patient's body. In 2001, the FDA also granted our application for the commercial sale of the fresh form of ORCEL for use on patients with recessive dystrophic epidermolysis bullosa undergoing hand reconstruction, as well as to treat the donor site wounds created during the surgery. Recessive dystrophic epidermolysis bullosa is a condition in which a newborn infant's skin instantly blisters and can peel off at the slightest touch and leave painful ulcerations and permanent scarring resulting in deformity of the hands and feet.

From December 2001 through December 2002, our gross revenues from the sale of ORCEL, using a limited contracted sales force, were \$265,665. We discontinued our sales efforts and the manufacture of fresh ORCEL for commercial sale preferring to use our limited financial resources for the completion of our clinical trial for the use of cryopreserved ORCEL

in the treatment of venous stasis ulcers. Based on published information we believe that the use of ORCEL for the treatment of patients suffering from venous stasis ulcers, and of patients suffering from diabetic foot ulcers, each represents a significantly larger potential market than the use of ORCEL for the treatment of donor site wounds or epidermolysis bullosa.

We completed a pivotal clinical trial for the use of ORCEL in its cryopreserved form for the treatment of venous stasis ulcers. Venous stasis ulcers are open lesions on the legs which result from the poor circulation of the blood returning from the legs to the heart. In February 2004, we filed with the Food and Drug Administration (FDA) our application for clearance to market ORCEL for the treatment of venous stasis ulcers. In the process of reviewing our application the FDA requested clarification of the various information provided by us. After a number of meetings we had with the FDA's staff and additional submissions we made to the FDA, on April 25, 2005 the FDA advised us that although our cryopreserved ORCEL showed promise for the effective treatment of venous stasis ulcers, additional clinical data would be required to demonstrate reasonable assurance of the safety and effectiveness of cryopreserved ORCEL in treating patients with venous stasis ulcers, before the FDA would clear ORCEL for commercial sales for such treatments. The clinical data from the pivotal trial of 136 patients submitted to the FDA showed that in 60 patients who had typical venous ulcers (defined as those ulcers with partial or full-thickness ulcers in which the wound base is visible and the ulcer extends through the dermis but not into the subcutaneous tissue to fascia, muscle or bone), 59% of the ORCEL treated patients achieved wound closure versus 36% of the patients who received the standard of care treatment. The FDA agreed that data of these 60 patients would be combined with that of the 60 patients to be enrolled in a confirmatory clinical trial and the combined results will be analyzed using Bayesian statistics. We obtained FDA approval for our confirmatory trial protocol in mid July 2005 and began the confirmatory trial in mid August 2005. We expect to complete enrollment for this clinical trial no later than April 2006. When the clinical trial is completed we will work towards obtaining regulatory clearance for commercial sales of cryopreserved ORCEL to treat venous stasis ulcers.

We have deferred conducting a pivotal clinical trial for the use of ORCEL in the treatment of diabetic foot ulcers until after FDA determination of whether we may make commercial sales of cryopreserved ORCEL to treat venous stasis ulcers. We completed a pilot clinical trial for the use of ORCEL, in its fresh, not cryopreserved, form in the treatment of diabetic foot ulcers in the latter part of 2001. The results of that clinical trial showed a 75% improvement over the standard of care as well as a daily healing rate that was twice as fast as the standard of care, for those patients treated with ORCEL. On January 6, 2005, we submitted a modified protocol to the FDA for the conduct of a clinical trial of cryopreserved ORCEL to treat diabetic foot ulcers. In February 2005, the FDA completed a review of our modified protocol and gave us permission to initiate a pivotal trial evaluating cryopreserved ORCEL in the treatment of diabetic foot ulcers. We expect to initiate patient enrollment for the diabetic foot ulcers pivotal clinical trial shortly after receiving FDA clearance for commercial sales of ORCEL in the treatment of venous stasis ulcers. We expect that the diabetic foot ulcers clinical trial will be conducted at up to 25 clinical centers and involve up to approximately 200 patients.

We have a Cell Therapy Manufacturing Agreement with Cambrex Bio Science Walkersville, Inc., a subsidiary of Cambrex Corporation (Cambrex), for Cambrex to produce ORCEL for us in Cambrex' production facilities in Walkersville, Maryland. Cambrex is experienced in producing cell based medical products such as ORCEL. Having Cambrex produce ORCEL for us alleviated the need for us to build and equip our own production and distribution facility, thus avoiding a large capital outlay, and we believe is otherwise more cost effective for us. We have also entered into a Sales Agency Agreement with Cambrex for Cambrex to be the exclusive distributor of ORCEL in the United States, Canada and Mexico. Our sales agency agreement with Cambrex requires Cambrex to spend \$4,000,000 in a sixteen month period to create a dedicated sales force for, and otherwise to arrange for the sale of ORCEL. That agreement also provides us with the major share of revenues from the sale of ORCEL, a dedicated sales force, and an amendment to our Cell Therapy Manufacturing Agreement with Cambrex resulting in a \$1,500,000 reduction in the amount we were required to contribute to building a larger production facility. We believe that our production and sales agreements with Cambrex will enable us to begin commercial sales of ORCEL in the United States shortly after, and if, we get clearance from the FDA to begin commercial sales of cryopreserved ORCEL for the treatment of venous stasis ulcers. During 2005, Cambrex further supported our efforts both through a \$200,000 investment in the January 2005 private placement and in agreeing to accept our common stock and warrants in exchange for approximately \$800,000 of production suite charges for the period May through October 2005. As of March 20, 2006, the common stock and warrants exchanged for the production suite charges in 2005 had not been issued. Additionally, for the period January through June 2006, Cambrex has agreed to accept our common stock and warrants in exchange for approximately \$800,000 of production suite charges.

While our immediate focus continues to be the commercialization of our core technology for chronic wounds and wound management, we continue to look at opportunities in which we can leverage our cell culturing biomaterials and regulatory knowledge and expertise to broaden our potential sources of revenue.

In October 2004 we entered into a collaboration agreement with Hapto Biotech Inc. (Hapto). Hapto is a privately-held company involved in the field of tissue engineering focused on the development of two proprietary fibrin derived platform

technologies: Fibrin Micro Beads (FMB's) and Fibrin based peptides (Haptides™), which have demonstrated the ability to optimize the recovery, potential delivery and therapeutic value of adult stem cells. Hapto's research indicates that FMB's have the ability to efficiently recover adult stem cells from mixed cell populations, as well as allow for their growth, proliferation and potential reimplantation into the patient. Hapto's research also indicates that Haptides™ have the ability to enhance cell attraction and attachment, as well as effect cellular internalization of macromolecules and nanoparticles, allowing for the potential development of products for the stem cell, tissue regeneration and tissue augmentation, gene therapy and drug delivery markets. The objective of the collaboration entered into in October 2004 was to combine our proprietary collagen biomaterial and know-how with Haptides™ to develop a non cellular peptide based collagen biomaterial which could promote the attraction and attachment of healthy cells within the patient's body in regenerating new tissue or repairing wounds. The collaboration's pre-clinical animal studies with this biomaterial showed promising results. Based on these promising results and the potential of the FMB's technology, on December 15, 2005, we executed a non-binding letter of intent to acquire Hapto, and all its fibrin based technology and intellectual property. On April 14, 2006, we completed the acquisition of Hapto after the acquisition was approved by Hapto's shareholders and we received commitments for over \$6,000,000 from a private placement sale of our equity securities. The receipt of such gross proceeds was a condition for the closing of our acquisition of Hapto. For such acquisition we issued to the Hapto shareholders a total of 30,860,000 shares of our common stock and warrants to purchase an additional 3,000,000 shares at \$0.30 per share. Rodman & Renshaw, LLC served as our advisor for this acquisition. On April 17, 2006, we completed the above private placement sale of our equity securities for aggregate proceeds of \$6,176,000.

Hapto has not conducted any human clinical trials to determine the safety and effectiveness in using FMB's or Haptides to treat human medical conditions. Hapto has performed research on the potential use of FMB's and Haptides in animal tests and in vitro testing and this data has been published. Hapto's research is conducted in Israel.

We believe that our experience and knowledge in the areas of cell biology, biomaterials and tissue regeneration provide a platform from which we can effectively expand our focus to include the development of stem cell and regenerative medicine products. In anticipation of receiving FDA approval during the next year to begin marketing our ORCEL product for the treatment of venous leg ulcers, we believe we should identify our future growth opportunities. Adding Hapto's technologies to our product and technology puts us in the growing field of stem cells and regenerative medicine. We believe Hapto's technologies and focus present an attractive opportunity for us and our shareholders.

Ortec was organized in 1991 under the laws of the State of Delaware for the purpose of acquiring, developing, testing and marketing our skin replacement product. Our executive offices are located at 3960 Broadway, New York, New York, and our telephone number is (212) 740-6999. Our website address is www.ortecinternational.com.

The Product

ORCEL is produced from cells derived from infant foreskins obtained during routine circumcisions. The immature, neonatal cells are highly reproductive and provide enhanced proliferation and rapid remodeling of the human skin. We separate the epidermis from the dermis and treat each of these layers to release individual keratinocyte (epidermal) and fibroblast (dermal) cells, which are the primary cellular components of human skin. We grow the fibroblast and keratinocyte cells in cultures in large quantities, then freeze and store them as a cell bank, ready for use. Prior to the use of each cell line, we conduct extensive testing and screening in accordance with current FDA guidelines to ensure that the cells are free of presence of bacterial contaminants, viruses, pathogens, tumorigenicity or other transmittable diseases. We then apply the dermal fibroblast cells to a proprietary, cross-linked bovine collagen sponge to form the dermal layer matrix and we grow the epidermal keratinocyte cells on a separate non-porous layer of collagen. We then incubate and supply this composite matrix with the proper nutrients to allow the cells to multiply and for the fibroblasts to permeate inside and anchor to the porous collagen sponge. The top layers of keratinocyte cells and bottom layers of fibroblast cells in the collagen matrix, together constitute our proprietary ORCEL.

Original Research

Dr. Mark Eisenberg, a physician in Sydney, Australia, developed our technology. Dr. Eisenberg is a director and one of our founders. He has been involved in biochemical and clinical research at the University of New South Wales in Australia for over twenty-five years, focusing primarily on treating the symptoms of epidermolysis bullosa. In 1987, through his work on epidermolysis bullosa, Dr. Eisenberg first succeeded in growing epidermal layers of human skin, which he successfully applied as an allograft on an epidermolysis bullosa patient. An allograft is a transplant other than with the patient's own skin. Dr. Eisenberg continued his research which eventually led to the development of ORCEL: a tissue-engineered dressing which consists of both the dermal and epidermal layers.

Government Regulation

We are subject to extensive government regulation. Products for human treatment are subject to rigorous pre-clinical and clinical testing procedures as a condition for clearance by the FDA and by similar authorities in foreign countries prior to commercial sale. Upon the completion of our current confirmatory clinical trial evaluating ORCEL for treatment of venous stasis ulcers we will again submit our PMA application to the FDA to determine whether we may make commercial sales of our product to treat venous stasis ulcers. However, it is not possible for us to determine whether the results from our human clinical trial will be sufficient to obtain FDA clearance.

The FDA Clearance Process

Pursuant to the Federal Food Drug and Cosmetic Act and regulations promulgated thereunder, the FDA regulates the manufacture, distribution and promotion of medical devices in the United States. ORCEL is considered by the FDA to be a medical device and is therefore regulated by the Center for Device and Radiological Health. We must receive pre-market clearance from the FDA for any commercial sale of our product. Before receiving such clearance we must provide proof in human clinical trials of the safety and efficacy of ORCEL. Pre-market clearance is a lengthy and expensive process.

The steps in the FDA clearance process may be summarized as follows:

- The sponsor (such as Ortec) prepares a protocol which sets forth in detail all aspects of the proposed clinical trial. The information includes the number of patients to be treated, the number of sites (hospitals and clinics) at which the patients in the clinical trial are to be treated, the then current standard of care with which the patients in the control group (in comparable medical condition as the patients to be treated with the medical device which is the subject of the clinical trial) are to be treated, the treatment frequency and the statistical plan that will be utilized to analyze the data derived from the clinical trial.
- The protocol also has to establish the safety of the use of the medical device to be studied in the trial. Safety can be established in a number of ways. One is by showing the results of use of the medical device in treatments in other clinical trials, in hospital approved treatments elsewhere in the world or by use in animal clinical trials and/or in an FDA cleared "pilot" clinical trial in which far fewer patients are treated than in the definitive "pivotal" clinical trial.
- The sponsor submits the protocol to the FDA.
- The FDA staff gives their comments, objections and requirements on the submitted protocol.
- The sponsor redrafts the protocol and otherwise responds to the FDA's comments.
- The sponsor recruits hospitals and clinics as sites at which the patients in the study are to be treated. Such recruitment begins with or prior to the preparation of the protocol.
- After the FDA clears the protocol the trial sites and the sponsor recruit the patients to be treated in the study.
- The patients are treated at not more than the number of trial sites specified in the protocol. One half of the patients are treated with the medical device being studied and the other half, the control group, with the then current standard of care for treatment of the same medical condition.
- The sites follow up each treated patient (for the period and the number of times provided in the FDA cleared protocol) to determine the efficacy of the medical device being studied in the treatment of the medical condition identified in the protocol, as against the efficacy of the standard of care used in the study.
- The sponsor assists and monitors compliance with the protocol's requirements in each site's conduct of the study.
- The sponsor collects the clinical data of each patient's treatment and progress from the sites.
- The data is analyzed by or for the sponsor. The sponsor prepares a report of the results of the study and submits the report and the supporting clinical data to the FDA staff reviewers for their comments and questions.

- After staff review of the submitted data, the sponsor responds to the FDA's comments and questions.
- After completion of its review, the FDA staff may submit a report of the results of the trial to an advisory medical panel consisting of experts in the treatment of the medical condition which the studied medical device is intended to treat.
- The panel submits its advice as to the efficacy and safety of the device to the FDA official who is the Director of the FDA Division to which the protocol and the results of the pivotal trial were originally submitted. If no advisory panel is required, the FDA staff reviewers submit their recommendation directly to the Division Director.
- The FDA Division Director is the FDA official who determines whether or not to clear the medical device for commercial sale for treatment of that medical condition. The sponsor may appeal a Division Director's negative determination through appeal levels within the FDA, up to the Commissioner of the FDA.
- After FDA clearance the sponsor must submit all labeling information for the medical device to the FDA to make certain that the claims on the label accurately state the uses for which the medical device has been cleared.

We have already discussed our pivotal clinical trial of the use of ORCEL in the study. There were 136 patients that were treated at 19 clinical sites in that study. We are currently completing a confirmatory clinical trial involving 60 patients to further test the safety and efficacy of cryopreserved ORCEL to treat venous stasis ulcers.

Regulatory Strategies

We employ a team of regulatory and clinical professionals, both full time employees and consultants, with extensive knowledge in strategic regulatory and clinical trial planning to support our product development efforts through every stage of the development and FDA clearance process. We also employ persons with extensive knowledge and experience in the marketing and sale of new FDA approved products for treatment of many medical conditions, including experience in securing approval of insurance companies to reimburse their insured patients for the cost of the use of new medical products used in medical treatments. We have secured approval for Medicare payments for the use of ORCEL under Medicare's Outpatient Prospective Payment System (OPPS) for approximately \$1,100 per ORCEL. This approval covers the use of ORCEL in hospitals, other hospital-owned facilities and for hospital outpatient treatment. However, we will still need to secure the approval of Medicare designated contractors in different parts of the country for approval of the different medical conditions for which Medicare reimbursement of the use of ORCEL will be made. We can only secure that further approval after we have received FDA clearance for use of ORCEL for the treatment of that medical condition. We will also seek to secure approval for private health insurance providers' reimbursement for the cost of ORCEL. We believe that securing Medicare reimbursement approval for ORCEL will be of significant assistance to us in securing reimbursement approval by private health insurance companies.

Sales and Marketing

As noted above, our business strategy is to combine our efforts with Cambrex for the production and commercial sale of ORCEL. On October 18, 2004, we entered into a Sales Agency Agreement with Cambrex, providing for Cambrex to be the exclusive sales agent in the United States for our ORCEL product or any other future bi-layered cellular matrix product of ours for the treatment of venous stasis ulcers, diabetic foot ulcers or any other therapeutic indication for dermatological chronic or acute wound healing. The agreement is for a period of six years beginning sixty days after we receive clearance from the FDA for the commercial sale of ORCEL for the treatment of venous stasis ulcers. The agreement requires us to pay commissions to Cambrex ranging from initially at 40% of net sales and decreasing to 27% of net sales as the amount of sales increases. The agreement requires Cambrex to spend \$4,000,000 for marketing efforts during the sixteen-month period after the FDA clears our sale of ORCEL for the treatment of venous stasis ulcers.

Cambrex had the right to terminate the agreement if we did not receive FDA clearance for commercial sale of ORCEL for the treatment of venous stasis ulcers by April 1, 2005 and has the right to terminate if for any period of six consecutive months beginning in 2007, sales are less than 9,000 units. We may terminate the agreement if sales of ORCEL are less in any twelve month period than amounts targeted in the agreement for that period (ranging from 10,000 units in the first twelve month period to 100,000 units in the sixth twelve month period). Although we did not receive FDA clearance by April 1, 2005, we have received no indication from Cambrex that they plan to terminate our agreement. During 2005, as noted earlier, Cambrex made equity investments in cash, and or in exchange for services, of approximately \$1,000,000.

Additionally, in 2006 Cambrex agreed to accept our common stock and warrants in exchange for an additional approximate \$800,000 of production suite charges.

Concurrent, and in connection with the Sales Agency Agreement, we entered into a License Agreement pursuant to which we licensed certain intellectual property rights to Cambrex. We also entered into a Security Agreement with Cambrex to secure the performance of our obligations under the Manufacturing, License, and Sales Agreement. The secured collateral consists of all accounts, cash, contract rights, payment intangibles, and general intangibles arising out of or in connection with the sale of products pursuant to the sales agreement and/or license agreement. The lien and security interest under this security agreement are subordinate and junior in priority to the perfected lien and security interest we granted to Paul Royalty Fund under the Paul Royalty Security Agreement.

In October 2003, we entered into an exclusive License Agreement with Teva Medical Limited, a subsidiary of Teva Pharmaceutical Industries Ltd. (Teva) for the sales and marketing of our ORCEL product in Israel. This ten-year agreement, beginning on the date the product is launched for marketing in Israel, requires Teva to seek regulatory and reimbursement approval for ORCEL in Israel. We received an upfront payment of \$50,000 in 2003 which we recorded as deferred income, see Note 6. We will receive an additional \$50,000 within thirty days of grant of reimbursement approval in Israel, and another \$100,000 within 30 days of attainment of aggregate net sales of \$3,000,000 in Israel within any period of twelve consecutive calendar months. The agreement also provides for ORCEL pricing and terms of payment. Additionally Teva will pay us royalties of 10% of net sales in Israel up to \$5,000,000 per annum. If sales are in excess of \$5,000,000 annually Teva will pay us 10% on the first \$5,000,000 of sales in Israel and a 20% royalty on sales above \$5,000,000 in Israel. As of December 31, 2005, regulatory and reimbursement approval have not been achieved.

We are currently also seeking agreements for the sale of ORCEL outside North America.

Production and Supply

On October 29, 2003, we entered into an agreement commencing November 1, 2003, with Cambrex for Cambrex to manufacture ORCEL in its Walkersville, Maryland facilities. The Cambrex manufacturing facility is required to meet FDA's good manufacturing processes standards. Cambrex is experienced in the manufacture of cell-based medical products such as our ORCEL. On October 18, 2004, in connection with our Sales Agency Agreement with Cambrex, we amended certain terms of this manufacturing agreement.

Our manufacturing agreement with Cambrex requires us to currently pay Cambrex \$132,613 per month, or approximately \$1,591,350 per year, for the use of a Cambrex production facility in Walkersville, Maryland. The payments we will make to Cambrex will increase to \$175,000 monthly, or \$2,100,000 per year, if we require Cambrex to build us a larger production facility to meet our requirements for the production of ORCEL. Such annual payments include some services and overhead expenses provided and paid for by Cambrex. These annual payments we are required to make increase 3% per annum on the anniversary of the commencement date. We are required to pay 50% of the cost of the construction of that larger production facility up to a maximum payment by us of \$1,000,000 (up to \$2,500,000 if we terminate our Sales Agency Agreement with Cambrex). However, the amount we contribute to the construction of that larger facility will be repaid to us by credits against a portion of the future annual payments and of certain other payments we are required to make to Cambrex after the larger facility is in use. We are also required to pay specified hourly charges for the Cambrex employees engaged in the production of ORCEL as well as certain other charges. After construction of the larger production facility we are required to acquire from Cambrex virtually all of our requirements for ORCEL that Cambrex can produce. Prior to our election to have Cambrex construct the larger production facility for us, either we or Cambrex may terminate the agreement on six months notice by us and twelve months notice by Cambrex. If we elect to have Cambrex construct the larger production facility for us the agreement will continue for six years after the larger production facility is constructed. However, even after such construction we and Cambrex may elect to scale down over the following three years the portion of our requirements for ORCEL that Cambrex will produce for us. We may elect the scale down period at any time after one year after the larger production facility is constructed and in operation in which event there are additional payments we must make to Cambrex. If we elect the scale down period after one year we must pay Cambrex \$2,625,000 and if we elect the scale down period after two years we must pay Cambrex \$1,050,000. If we elect the scale down periods in either of those two years, we forfeit our right to receive any further credits (up to the amount of our contribution to the cost of the larger production facility) against payments we are thereafter required to make to Cambrex. Either Cambrex or we may elect the scale down period later than three years after that facility is in operation and neither of us will be required to make any additional payments to the other because of that election.

If after the construction of the larger production facility, we breach a material term of our agreement with Cambrex, or elect to terminate the agreement, we will have to pay Cambrex the following amounts:

<u>If termination occurs after the following anniversary of the construction of the larger production facility</u>	<u>Amount of Payment</u>
6 years	\$1,050,000
5 years, but less than 6 years	1,575,000
4 years, but less than 5 years	2,625,000
3 years, but less than 4 years	3,675,000
2 years, but less than 3 years	5,250,000
1 year, but less than 2 years	6,300,000

In addition, upon such termination we will forfeit our right to receive any further credits (up to the amount of our contribution to the cost of the larger production facility) against future payments we may have to make to Cambrex.

The raw materials that we use to manufacture ORCEL come from a limited number of suppliers. We currently purchase collagen corium, a component of the collagen matrix in ORCEL, from a single supplier but we are in the process of securing a secondary source of supply for that item. The collagen matrix used in ORCEL is manufactured for us to our specifications by another supplier, and we are in the process of identifying a secondary source for collagen matrix also. On December 30, 2004 we entered into a two-year supply agreement with the manufacturer of the collagen matrix. We agreed to purchase a minimum of 3,500 units of finished collagen sponges within the first twelve-month period. The value of such commitment is approximately \$200,000. Such commitment was not achieved in 2005 and we were released from any resulting liability by the supplier. We also agreed that subsequent to a written notification from the FDA allowing us to sell ORCEL commercially for treatment of venous stasis ulcers we will provide such supplier projections for one or more subsequent quarters and the parties will be obligated to purchase and sell those projected amounts. While there may be other sources from where we could purchase such materials, a disruption in the supply chain for any of those materials would have a significant negative impact on our ability to manufacture and sell ORCEL and in any event would likely cause us delays and additional expenses in the manufacturing of ORCEL.

During 2004 we also announced an agreement with ES Cell International Pte, Ltd (ESI) to collaborate in the development of ESI's human Embryonic Stem Cell (hES) derived cell therapy products. Under the terms of the agreement, we will supply ESI with human skin cells generated from cell lines developed and manufactured by us for our ORCEL product. We have conducted extensive testing for viruses of the cells we are providing to ESI in accordance with FDA guidelines. ESI will use the cells we provide in research and development and in commercialization of their stem cell products. Under the terms of the agreement, we have received upfront payments and may receive additional payments on the achievement of milestones in ESI's human hES cell derived cell therapy programs. The agreement also provides for payment of royalties to us from future commercial sales of ESI's cell therapy products.

Competition

We are aware of several companies that are actively engaged in the research and development of products for the repair and regeneration of skin. There are currently three primary and distinct approaches to the repair and regeneration of skin: the acellular (no cell) approach, including the use of cadaver based products; the cell-based unilayered (epidermal or dermal cell) approach, and the cell-based bi-layered (epidermal and dermal cell) approach. A cell-based approach makes use of human donor cells. The approach we believe to be the most advanced and effective is the cell-based bi-layered approach. The production of ORCEL consists of a top layer of epidermal cells and a bottom layer of dermal cells in a collagen matrix, that is a bi-layered approach utilizing donor cells.

There are many products available for treating skin wounds. However, as already noted, we believe that the use of donor cells delivered to the wound on a matrix is the most effective process for healing skin wounds and in particular hard to heal skin wounds. Therefore, we believe that only products using donor cells placed on a matrix will compete with ORCEL.

We consider the Apligraf product manufactured by Organogenesis, Inc. to be our principal competitor. Apligraf is an FDA cleared product using human dermal and epidermal cells (bi-layered) placed on a matrix, for the treatment, of both venous stasis and diabetic foot ulcers. The Apligraf product is not cryopreserved and has reported it has a shelf life of 10 days. Organogenesis, Inc. is a private company that markets and sells their own product. Although financial information has to our knowledge not been publicly disclosed we believe Organogenesis has greater resources than we have.

The biomedical field is continually undergoing rapid and significant technological changes. Other companies may succeed in developing other products that are more effective than ORCEL. If such new products are accepted by the medical community, or if those products receive FDA approval for treatment of venous stasis and diabetic foot ulcers before ORCEL does, or if other companies develop products that are more effective than ORCEL, any such developments could impede our ability to continue our operations.

Patents and Proprietary Rights

We have four United States patents, one European patent covering thirteen countries, and ten patents in ten other countries, issued. We also have one United States and eight international patent applications (filed under the Patent Cooperation Treaty) pending for our technology and processes:

- The first of these patents covers the structure of ORCEL. It is an epidermal layer of cultured epidermal cells and a bilayered collagen sponge structure that includes a layer of highly purified, non-porous collagen on top of a porous cross-linked collagen sponge containing cultured dermal cells. This patent expires on February 1, 2011. This is also the technology covered by the European and other foreign patents which have been issued to us. These foreign patents also expire in 2011.
- Another United States patent provides for the extension of the use of the collagen sponge structure described above which may contain cells other than epidermal and/or dermal cells, such as cells for regenerating such organs and tissues as heart muscle, blood vessels, ligaments, cartilage and nerves. This patent also expires on February 1, 2011. We have not performed, nor are we planning to perform in the near future, any clinical trial using our platform technology for use of donor cells other than epidermal and dermal cells.
- Another United States patent covers a manufacturing process which, when implemented, can reduce the cost of producing ORCEL. This new manufacturing process creates an improvement over our collagen structures described above in that a third layer of collagen which is hospitable to cell growth is deposited on the non-porous collagen layer. This patent expires on December 28, 2020.
- Our fourth United States patent covers a process for the cryopreservation of ORCEL. This patent expires on December 26, 2021.
- We have filed a divisional patent application of the cryopreservation process patent to add claims to cover the cryopreserved form of ORCEL and we are awaiting an office action from the U.S. Patent Office.

Despite such patents our success will depend, in part, on our ability to maintain trade secret protection for our technology.

We successfully defended challenges by Organogenesis to our United States patent and by Advanced Tissue Sciences to our European patent in the respective patent offices where those patents were issued. However, those successful defenses do not preclude future challenges in court. We do not know if any of the other patents issued to us will be challenged, invalidated or circumvented. Patents and patent applications in the United States may be subject to interference proceedings brought by the U.S. Patent and Trademark Office, or to opposition proceedings initiated in a foreign patent office by third parties or to re-examination proceedings in the United States. We might incur significant costs defending such proceedings and we might not be successful.

The validity and breadth of claims in medical technology patents involves complex legal and factual questions and, therefore, are highly uncertain. We do not know if any pending patent applications or any future patent application will issue as patents, that the scope of any patent protection obtained will be enough to exclude competitors or that any of our patents will be held valid if subsequently challenged in court proceedings. We do not know if others have or will develop similar products, duplicate any of our products or design around any of our patents issued or that may be issued in the future. In addition, whether or not patents are issued to us, others may hold or receive patents which contain claims having a scope that covers aspects of our products or processes.

Several of our competitors have been granted patents, including those granted to Organogenesis and Advanced Tissue Sciences, Inc., relating to their particular skin technologies which also utilize donor cells on a collagen sponge matrix. To that extent they may be considered similar to our ORCEL technology.

Paul Royalty Fund Agreement

In August 2001 and in 2002, we entered into agreements with Paul Royalty Fund, L.P. (PRF) pursuant to which we agreed in consideration of PRF paying us \$10,000,000, to pay to PRF 3.33% of the end user sales prices paid for our ORCEL product in the United States, Canada and Mexico through the period ending in 2011. Such percentage interest in our revenues in those three countries may be adjusted upward or downward based on the volume of sales to end users of ORCEL in those three countries. As security for the performance of our obligations to PRF, we have granted PRF a security interest in all of our U.S. patents, patent applications and trademarks. Our agreement with PRF provides that in certain events PRF may, at its option, compel us to repurchase the interest in our revenues that we sold to PRF for a price equal to the \$10,000,000 PRF paid us plus an amount that would yield PRF a 30% per annum internal rate of return on its \$10,000,000 investment. Among the events that would entitle PRF to compel us to repurchase its interest in our revenues at that price is if we are insolvent or if we are unable to pay our debts as they become due. Our agreement with PRF provides that in determining such insolvency any amount we owe to PRF is excluded in calculating our net worth (or negative net worth). In addition, although we are currently trying to manage our debt we are not paying our debts as they become due. As defined in our agreement with PRF we are currently insolvent. As a result of this insolvency our obligation under the revenue interest assignment is stated at \$29,569,000, the amount PRF could compel us to repurchase their revenue interest at December 31, 2005. In December 2004, PRF entered into a forbearance agreement with us agreeing that they cannot exercise their right to compel us to repurchase their interest in our revenues because of our insolvency prior to July 2006. If PRF exercised its right to compel us to repurchase its interest in our revenues and we did not have the funds to pay the purchase price, PRF could foreclose its security interest in our U.S. patents, patent applications and trademarks and in such event we may have to discontinue our business operations.

The agreement with PRF is more fully described in Note 10 of the accompanying financial statements. As described in Note 10, in accordance with accounting promulgated by Statements of Financial Accounting Standards No. 15, "Accounting by Debtors and Creditors for Troubled Debt Restructurings" (SFAS 15) even if we are no longer insolvent as long as our future cash payments relating to the revenue interest assignment obligation are indeterminate, the revenue interest assignment obligation would remain at the value that achieves the 30% internal rate of return for PRF through the last date of our insolvency. We believe that it is highly improbable we will ever owe PRF the amount of this obligation.

SFAS 15 allows debtors that can predict with certainty the absolute amounts of future cash flow payments to record an immediate gain if the maximum future cash payments are less than the carrying amount of the obligation. In the case where the future cash payments are indeterminate, as ours are considered, the gain is not recognized until the end of the term of the outstanding debt, December 31, 2011, or upon termination. We estimate that we would need to achieve a North American sales level of approximately \$1,160,000,000 during the approximate remaining five sales years under the revenue interest assignment agreement to offset the principal balance of the \$29,569,000 revenue interest obligation. We are prohibited by SFAS 15 from making a reasonable estimation of our future sales to assess the amount of our future debt payments and therefore are precluded from reducing the liability and recognizing a gain at this time. We believe we will likely record a gain on the revenue interest assignment obligation to PRF in 2011 or upon termination, if sooner.

Research and Development Expenses

Research and development expenses consist primarily of salaries; amounts paid to Cambrex, facility costs and laboratory supplies. Research and development expenses were \$7,535,532 for the year ended December 31, 2005, compared to \$7,139,733 for the year ended December 31, 2004.

Compliance with Environmental Regulations

We are subject to regulation under the Occupational Safety and Health Act, the Environmental Protection Act, the Toxic Substances Control Act, the Resource Conservation and Recovery Act, the Controlled Substances Act and other present and potential future federal, state or local regulations. Our research and development programs involve the controlled use of hazardous materials, chemicals, biological materials and various radioactive compounds.

Although we believe that our operations comply in all material respects with applicable environmental laws and regulations, the risk of accidental contamination or injury from these materials cannot be completely eliminated. In the event of such an accident, we could be held liable for any damages that result, and the extent of that liability could exceed our resources. Our compliance with these laws and regulations did not, and is not expected to, have a material effect upon our capital expenditures, earnings or competitive position.

Employees

We presently employ 36 people on a full-time basis, including four executive officers. We also have six part-time employees.

Available Information

Our annual reports on Form 10-KSB, quarterly reports on Form 10-QSB, current reports on Form 8-K and all amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 are available free of charge on our website (www.ortecinternational.com) as soon as reasonably practicable after they are filed with, or furnished to, the Securities and Exchange Commission.

PART II

Item 5. MARKET FOR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

Market Information

Our common stock commenced trading on January 19, 1996, under the symbol "ORTC." The common stock traded on the NASDAQ Small Cap market until August 2002, when it was delisted from the Small Cap market and commenced trading on the National Association of Securities Dealers' Bulletin Board, where it presently trades under the symbol "ORTN.OB." The following table sets forth the high and low sales prices of our common stock as reported by the Bulletin Board for each full quarterly period within the two most recent fiscal years.

	<u>HIGH</u>	<u>LOW</u>
<i>2005 Quarter</i>		
First	\$1.19	\$0.63
Second	0.88	0.27
Third	0.40	0.24
Fourth	0.35	0.17
<i>2004 Quarter</i>		
First	3.55	1.95
Second	2.95	2.05
Third	2.40	1.35
Fourth	2.30	0.89

Security Holders

To the best of our knowledge, at March 3, 2006, there were 317 record holders of our common stock. We believe there are more than 1,800 beneficial owners of our common stock whose shares are held in "street name."

Dividends

We have not paid and have no current plans to pay dividends on our common stock. Under of our Agreement with Paul Royalty Fund we agreed not to issue any new debt or equity securities that contain cash dividend or mandatory redemption provisions.

Recent Sales of Unregistered Securities

In addition to our unregistered sales of our equity securities during the three-month period ended December 31, 2005, which we reported on Forms 8-K, in that three-month period we have also sold and/or issued our equity securities which were not registered under the Securities Act of 1933, as amended (the "Act"), in the transactions described below. No underwriters were involved in any of these transactions.

- (a) On October 18, 2005, in partial consideration for services rendered by it to us we granted one company three-year warrants to (i) purchase 25,000 shares of our common stock at an exercise price of \$1.00 per share, which vested immediately upon our extension of the original three-month term of their service agreement. The grant of such warrants was exempt from the registration requirements of the Act pursuant to the provisions of Section 4(2) of the Act as a transaction by an issuer not involving any public offering.
- (b) On December 1, 2005, in partial consideration for services rendered by the same company to us we granted that company three-year warrants to (i) purchase an additional 25,000 shares of our common stock at an exercise price of \$0.50 per share, which warrants will vest on March 31, 2006, and (ii) to purchase an additional 25,000 shares of our common stock at an exercise price of \$1.00 per share, which vest only if we and the service provider extend the original three-month term of the service agreement beyond March 31, 2006. The grant of such warrants was exempt from the registration requirements of the Act pursuant to the provisions of Section 4(2) of the Act as a transaction by an issuer not involving any public offering.

Item 6. MANAGEMENT'S PLAN OF OPERATION

The following discussion should be read in conjunction with our financial statements and notes thereto. This discussion may be deemed to include forward-looking statements.

Plan of Operation

We are a development stage enterprise which had no operating revenue prior to December 2001. During 2001, we received Food and Drug Administration approval for the use of the fresh form of ORCEL for the treatment of patients with recessive dystrophic epidermolysis bullosa and for donor sites in burn patients. We began marketing and selling our product for use on patients with one of these indications using a contracted sales organization. Our sales and marketing efforts were active only for a brief period and accordingly our revenues were not significant. We terminated our sales efforts and elected to focus our attention on completing development of a cryopreserved form of our product for treatment of chronic wounds affecting larger populations. As a result, we completed a clinical trial during 2003 for the use of the cryopreserved form of ORCEL to treat venous stasis ulcers and filed an application for pre-market approval (PMA) with the FDA in February 2004. In a letter dated April 25, 2005, although the FDA concluded that cryopreserved ORCEL showed promise for the effective treatment of venous stasis ulcers, the FDA determined that additional data would be necessary, to confirm cryopreserved ORCEL's effectiveness and safety treating venous stasis ulcers. The clinical data from the pivotal trial of 136 patients submitted to the FDA showed that in 60 patients who had typical venous ulcers (defined as those ulcers with partial or full-thickness ulcers in which the wound base is visible and the ulcer extends through the dermis but not into the subcutaneous tissue to fascia, muscle or bone), 59% of the ORCEL treated patients achieved wound closure versus 36% of the patients who received the standard of care treatment. The FDA agreed that data of these 60 patients would be combined with that of the 60 patients to be enrolled in a confirmatory clinical trial and the combined results will be analyzed using Bayesian statistics. We obtained FDA approval for our confirmatory trial protocol in mid July 2005 and began the confirmatory trial in mid August 2005. We expect to complete enrollment for this clinical trial no later than April 2006. Our plan of operation for the next twelve months is to complete such clinical trial and continue to work towards obtaining regulatory clearance for commercial sales of cryopreserved ORCEL to treat venous stasis ulcers. In the interim, we are working with Cambrex Bio Science Walkersville, Inc., a subsidiary of Cambrex Corporation (Cambrex) to limit expenditures under our manufacturing agreement primarily to those which are essential for conducting the trial. Together, we are working on process improvements that we expect will drive down the cost of ORCEL as we plan for the potential commercialization of our product. During 2005, Cambrex further supported our efforts both through a \$200,000 investment in the January 2005 private placement and for the period May through October 2005, agreeing to accept our common stock and warrants in exchange for approximately \$800,000 of production suite charges. The common stock and warrants exchanged for the production suite charges have not yet been issued.

We have deferred conducting a pivotal clinical trial for the use of ORCEL in the treatment of diabetic foot ulcers until after FDA determination of whether we may make commercial sales of cryopreserved ORCEL to treat venous stasis ulcers. We completed a pilot clinical trial for the use of ORCEL, in its fresh, not cryopreserved, form in the treatment of diabetic foot ulcers in the latter part of 2001. The results of that clinical trial showed a 75% improvement over the standard of care as well as a daily healing rate that was twice as fast as the standard of care, for those patients treated with ORCEL. On January 6, 2005, we submitted a modified protocol to the FDA for the conduct of a clinical trial of cryopreserved ORCEL to treat diabetic foot ulcers. In February 2005, the FDA completed a review of our modified protocol and gave us permission to initiate a pivotal trial evaluating cryopreserved ORCEL in the treatment of diabetic foot ulcers. We expect to initiate patient enrollment for the diabetic foot ulcers pivotal clinical trial shortly after receiving FDA clearance for commercial sales of ORCEL in the treatment of venous stasis ulcers. We expect that the diabetic foot ulcers clinical trial will be conducted at up to 25 clinical centers and involve up to approximately 200 patients.

In the past twelve months, in anticipation of commercialization of ORCEL, operations were focused towards finalizing the ORCEL production process at Ortec and transferring the commercial manufacturing operations to Cambrex. During this time we enhanced and partially validated the ORCEL production process at Ortec allowing for the transfer of the production process and full validation at Cambrex. We submitted our manufacturing process to the FDA as part of the PMA application and received no significant comments from the FDA. We transferred the ORCEL manufacturing process to Cambrex and have worked with Cambrex in validating our production process of ORCEL at Cambrex. Work was also ongoing in the area of process development to improve the consistency, increase the scale and reduce the cost of producing ORCEL. To improve the consistency of ORCEL, we improved the process for the production of collagen sponges at our collagen sponge contract manufacturer, and identified a "BSE-free" source of corium for collagen. To increase scale and reduce the cost of manufacturing ORCEL, we developed a cell factory process to provide for the ability to accomplish larger scale cell expansion which will facilitate the production of additional cell inventory. The cell factory project is expected to be completed in June 2006. Development efforts were also ongoing to improve the process, and reduce the cost of producing our collagen sponge matrix, which included developing alternative sources of supply of bovine hide collagen and various grades of sponges that could provide new business opportunities. We validated several assay methods used to

qualify incoming raw materials and to monitor both the ORCEL production process and the final ORCEL product, all required by the FDA. Manufacturing cost reduction projects of longer duration may be delayed, or may be accomplished in collaboration with Cambrex. Preliminary discussions with Cambrex have taken place with respect to the transfer of our cell expansion processes as well as co-development of longer duration cost reduction and increased production process projects. The costs associated with these projects will be negotiated with Cambrex.

The following is a listing of the projected development activities on which we expect to focus during the next twelve months:

- Development and transfer to Cambrex of a process which doubles the ORCEL production lot size,
- Production and expansion of cell inventory,
- Completion of development of the cell factory project,
- Completion of all FDA required tests and validations, and
- Validation of "BSE-free" collagen.

We expect that the above projects will require our current level of staffing. We periodically review and adjust our staffing levels and operational expenses for maximum efficiency.

Additionally we plan to:

- acquire Hapto and expand our focus to application of our technologies to opportunities in regenerative medicine such as stem cells, wound healing, and cosmetic tissue augmentation;
- explore opportunities where we can use our FDA approved facility, cell culturing biomaterials and regulatory knowledge and expertise as an income source or to secure interests in other company's biotechnology products or in their business operations;
- Examine potential licensing opportunities for use of our biomaterials in other tissue engineering applications;
- Pursue co-development opportunity using growth factor media in development of cosmeceutical product, and
- Submit proposals to the appropriate agencies for the purpose of securing available research grants.

We may invest approximately \$125,000 for equipment which will allow us to expand our collagen sponge manufacturing capacity.

We do not presently expect any significant changes in personnel in 2006.

Letter of Intent to Acquire Hapto Biotech

On December 15, 2005 we executed a non-binding letter of intent to acquire Hapto Biotech (Hapto), a privately-held company involved in the field of tissue engineering focused on the development of two proprietary fibrin derived platform technologies: Fibrin Micro Beads (FMB's) and Fibrin based peptides (Haptides™), which have demonstrated the ability to optimize the recovery, potential delivery and therapeutic value of adult stem cells. Hapto's research indicates that FMB's have the ability to efficiently recover adult stem cells from mixed cell populations, as well as, allow for their growth, proliferation and potential reimplantation into the patient. Hapto's research also indicates that Haptides™ have the ability to enhance cell attraction and attachment, as well as effect cellular internalization of macromolecules and nanoparticles, allowing for the potential development of products for the stem cell, tissue regeneration and tissue augmentation, gene therapy and drug delivery markets.

We closed our acquisition of Hapto on April 14, 2006. For such acquisition we issued a total of 30,860,000 shares of our common stock to the Hapto shareholders and granted them warrants to purchase an additional 3,000,000 of our common shares at \$0.30 per share. The investment banking firm of Rodman & Renshaw, LLC acted as our advisor in this acquisition.

Other Liquidity Matters

Our agreement with Paul Royalty Fund (PRF) provides that in certain events PRF may, at its option, compel us to repurchase the interest in our revenues that we sold to PRF for a price equal to the \$10,000,000 PRF paid us plus an amount that would yield PRF a 30% per annum internal rate of return on its \$10,000,000 investment. Among the events that would entitle PRF to compel us to repurchase its interest in our revenues at that price is if we are insolvent or if we are unable to pay our debts as they become due. Our agreement with PRF provides that in determining such insolvency any amount we owe to PRF is excluded in calculating our net worth (or negative net worth). In addition, although we are currently trying to manage our debt we are not paying our debts as they become due. As defined in our agreement with PRF we are currently insolvent. As a result of this insolvency our obligation under the revenue interest assignment is stated at \$29,569,000, the

amount PRF could compel us to repurchase their revenue interest at December 31, 2005. Although in December 2004 we entered into an eighteen-month forbearance agreement providing that PRF would not prior to July 1, 2006 compel us to repurchase its interest in our revenues because of our insolvency, as of December 31, 2005 we were still considered insolvent and therefore were required to record as an obligation we owe PRF the amount to provide PRF with a 30% internal rate of return on its \$10,000,000 investment. If in the future PRF exercised its right to compel us to repurchase its interest in our revenues and we did not have the funds to do so, PRF could foreclose its security interest in our U.S. patents, patent applications and trademarks and in such event we may have to discontinue our business operations. Outside of a repurchase event, more fully explained in Note 10 of the consolidated financial statements, PRF would be entitled to the applicable royalty percentages of our future revenues in North America. We estimate that we would need to achieve a North American sales level of approximately \$1,160,000,000 during the approximate remaining five sales years under the revenue interest assignment agreement to offset the principal balance of the \$29,569,000 revenue interest obligation. We are prohibited by SFAS 15 from making a reasonable estimation of our future sales to assess the amount of our future debt payments and therefore are precluded from reducing the liability and recognizing a gain at this time. We believe we will likely record a gain on the revenue interest assignment obligation to PRF in 2011 or upon termination, if sooner.

We will need to secure additional financing for the approximately \$850,000 of cash we are currently consuming per month. The amount of cash we consume each month fluctuates, depending, among other things, on whether we are incurring expenses from services provided by third party suppliers in connection with a clinical trial and what payments we have to make on our outstanding debt.

As of December 31, 2005, payment of approximately \$1,354,000 of the approximately \$1,980,000 we owed to our trade creditors was past due. We have entered into agreements with creditors to whom we owe an aggregate of \$736,000 (as of December 31, 2005) to pay \$471,000 in 2006 and \$265,000 in 2007.

While we have arranged for payment of some of our obligations over a period of time, and have to make other payments of past due obligations to our current and ongoing suppliers, our ability to make payments we have agreed to pay and to insure continued receipt of needed supplies, and to continue reducing our past due obligations, will depend on our ability to secure needed financing or our ability to issue equity in satisfaction of certain obligations.

We hope to obtain additional funds through the sale of our securities to the public and through private placements, debt financing or other short-term loans. We may not be able to secure any financing nor may we be able to reach the larger patient population markets of persons with venous stasis ulcers and diabetic foot ulcers, with funds that we may be able to raise. We are also likely to continue to encounter difficulties which are common to development stage companies, including unanticipated costs relating to development, delays in the testing of products, regulatory approval and compliance and competition.

Our capital funding requirements depend on numerous factors, including:

- the progress and magnitude of our research and development programs;
- the time involved in obtaining regulatory approvals for the commercial sale of our ORCEL product in its cryopreserved form to treat venous stasis ulcers and, later, diabetic foot ulcers;
- the costs involved in filing and maintaining patent claims;
- technological advances;
- competitive and market conditions;
- the successful implementation of the agreements we have entered into with Cambrex for manufacturing and sales of our ORCEL product;
- our ability to establish and maintain other collaborative arrangements and
- the cost and effectiveness of commercialization activities and arrangements.

Unless we obtain additional financing we will not be able to continue to operate our business.

On March 17, 2006, we settled a vendor liability of approximately \$102,000 for \$35,000 cash payable in seven equal monthly installments and a three-year warrant to purchase 285,000 shares of our common stock at an exercise price of \$0.25. The warrant has piggyback registration rights.

In March 2006, we received \$380,000 of short-term loans from two entities. One loan for \$130,000 was from one of our executive officers, is non-interest bearing and is payable from the proceeds of our recent private placement of our securities. The second loan for \$250,000 bears interest at 8% per annum and was from the investor who had committed to provide us with \$1,058,000 by the later of the filing of our pre-market approval application for our confirmatory venous leg ulcer trial, or March 31, 2006. This \$250,000 loan automatically converted into the equity securities we issued in our recent private placement, at 1.2 times the principal and accrued interest amount. Additionally we agreed that upon conversion of

such \$250,000 loan to our equity securities, since the investor provided us with the funds earlier than was required, we would forego such investor's \$808,000 remaining commitment and that the earlier repricing (upon commitment) of our warrants held by such investor would not be affected.

On March 31, 2006, we received \$65,000 in a short-term loan from our executive officers, of which \$35,000 was repaid on April 6, 2006. On April 3, 2006 we received another short-term loan of \$45,000 from another of our executive officers. Both of these loans will be repaid from the proceeds of our recent private placement. On April 17, 2006, with the completion of our recent private placement, we converted the \$250,000 short-term loan with its then outstanding loan balance of \$301,333 into 301.33 shares of our Series E Preferred Stock, and issued a warrant to purchase 1,506,665 shares of our common stock at an exercise price of \$0.50 per share. On April 5, 2006 we received a \$200,000 short-term loan due April 30, 2006 to be repaid at 110% of principal plus accrued interest at 8% per annum on the original \$200,000 principal balance. We issued a three-year warrant to purchase 50,000 shares of our common stock at an exercise price of \$0.50 per share to the lender.

On April 17, 2006, we completed a private placement sale for aggregate gross proceeds of \$6,176,000 to accredited investors of our 6% Series E Convertible Preferred Stock and warrants to purchase our common stock. The Series E Convertible Preferred Stock is entitled to vote on an "as converted" basis on all matters submitted to a vote by the holders of the common stock. At any time these investors can convert their preferred stock into common stock at a \$0.20 conversion price. If we complete a reverse split of our outstanding common stock by June 16, 2006, the investors are obligated to convert their preferred stock on the 21st trading day following such reverse split by dividing the amount they paid for such preferred shares plus dividends at 6% per annum, by the lesser of \$0.20, or 90% of the average of the volume weighted average prices for our common stock for the twenty trading days following the effective date of such reverse stock split. We issued a five-year warrant to purchase our common stock at \$0.50 per share, for the number of common shares equal to the purchase price paid for our convertible preferred shares divided by \$0.20, or warrants to purchase an aggregate of 30,880,000 of our common shares. The warrants carry full ratchet price reset provisions should we sell our common stock or our other securities convertible into, or exercisable for, our common stock, at an effective price per common share less than the \$0.50 exercise price of the warrants. We are obligated to register, under the Securities Act of 1933, all of the shares of our common stock issuable upon conversion of the 6% Series E Convertible Preferred Stock, or upon exercise of such warrants. We will pay investors 2% per month for any failure to timely file by June 18, 2006 or obtain an effective registration statement by August 17, 2006.

Off-Balance Sheet Arrangements

We had no off-balance sheet arrangements as of December 31, 2005.

ORTEC INTERNATIONAL, INC.
(A DEVELOPMENT STAGE ENTERPRISE)
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

	<u>Page</u>
Report of Independent Registered Public Accounting Firm – BDO Seidman, LLP	F-2
Report of Independent Registered Public Accounting Firm – Grant Thornton LLP	F-3
Consolidated Balance Sheet as of December 31, 2005	F-4
Consolidated Statements of Operations for the years ended December 31, 2005 and 2004, and for the cumulative period from March 12, 1991 (inception) to December 31, 2005	F-5
Consolidated Statements of Shareholders' Equity (Deficit) for the cumulative period from March 12, 1991 (inception) to December 31, 2005	F-6
Consolidated Statements of Cash Flows for the years ended December 31, 2005 and 2004, and for the cumulative period from March 12, 1991 (inception) to December 31, 2005	F-11
Notes to Consolidated Financial Statements	F-13

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Stockholders
Ortec International, Inc.
New York, New York

We have audited the accompanying consolidated balance sheet of Ortec International, Inc. (a development stage enterprise) as of December 31, 2005 and the related consolidated statements of operations, shareholders' deficit, and cash flows for the years ended December 31, 2005 and 2004 and for the period from March 12, 1991 (inception) to December 31, 2005. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audit. We did not audit the consolidated statements of operations, shareholders' deficit and cash flows for the period from March 12, 1991 (inception) to December 31, 2003, which reflect product revenue of approximately \$3 million, expenses of approximately \$96.9 million, preferred stock dividends and discounts of approximately \$6.7 million, cash used in operating activities of \$69.9 million, cash used in investing activities of approximately \$6.2 million and cash provided by financing activities of \$77.4 million. Those financial statements were audited by another auditor whose report has been furnished to us, and our opinion, insofar as it relates to the amounts included for such period, is based solely on the report of the other auditor.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit and the report of the other auditor provide a reasonable basis for our opinion.

In our opinion, based on our audit and the report of the other auditor, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Ortec International, Inc. at December 31, 2005, and the results of the Company's operations and cash flows for the years ended December 31, 2005 and 2004 and for the period from March 12, 1991 (inception) to December 31, 2005, in conformity with accounting principles generally accepted in the United States.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1, the Company incurred a net loss applicable to common shareholders of \$36 million during the year ended December 31, 2005, and, as of that date, the Company's current liabilities exceeded its current assets by \$32.2 million, its total liabilities exceeded its total assets by \$31.3 million and the Company has a deficit accumulated in the development stage of \$156.4 million. These factors, among others, as discussed in Note 1 to the consolidated financial statements, raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ BDO Seidman, LLP

New York, New York

March 30, 2006, except for Notes 14 and 18 to the consolidated financial statements,
as to which the dates are April 14 and 17, 2006

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Directors and Shareholders
Ortec International, Inc.

We have audited the accompanying consolidated statements of operations, shareholders' equity (deficit) and cash flows for the period from March 12, 1991 (inception) through December 31, 2003 of Ortec International, Inc. and Subsidiary (a development stage enterprise) (the "Company"). These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the results of Ortec International, Inc. and Subsidiary's operations, changes in shareholders' equity (deficit) and cash flows for the period from March 12, 1991 (inception) through December 31, 2003, in conformity with accounting principles generally accepted in the United States of America.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the 2003 financial statements, the Company incurred a net loss applicable to common shareholders of \$21,449,131 during the year ended December 31, 2003, and, as of that date, the Company's current liabilities exceeded its current assets by \$25,360,740, its total liabilities exceeded its total assets by \$24,476,407, and the Company has a deficit accumulated in its development stage of \$103,307,740. These factors, among others, as discussed in Note 1 to the 2003 financial statements, raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1 to the 2003 financial statements. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ GRANT THORNTON LLP

New York, New York

March 12, 2004, except for Note 14 to the 2003 financial statements,
as to which the date is March 23, 2004

ORTEC INTERNATIONAL, INC.
(A DEVELOPMENT STAGE ENTERPRISE)
CONSOLIDATED BALANCE SHEET

December 31,
2005

ASSETS

Current assets:	
Cash and cash equivalents	\$ 675,389
Prepaid and other current assets	151,973
Total current assets	827,362
Property and equipment, net	198,331
Patent application costs, net	547,335
Deposits and other assets	156,876
Total assets	<u>\$ 1,729,904</u>

LIABILITIES AND SHAREHOLDERS' DEFICIT

Current liabilities:	
Accounts payable and accrued expenses	\$ 3,359,323
Capital lease obligation—current	13,405
Current maturities of promissory notes	41,635
Obligation under revenue interest assignment	29,569,000
Total current liabilities	32,983,363
Promissory notes, less current portion	50,082
Capital lease obligation, less current portion	9,949
Total liabilities	33,043,394
Commitments and Contingencies	
Shareholders' deficit:	
Preferred stock, \$.001 par value; authorized, 1,000,000 shares:	
Convertible Series D, stated value \$10,000 per share; authorized 10,000 shares; 6,272 shares issued and outstanding; liquidation preference of \$25,088,062	15,911,331
Common stock, \$.001 par value; authorized, 200,000,000 shares; 51,104,951 shares issued and 51,102,951 outstanding	51,106
Additional paid-in capital	109,775,884
Deficit accumulated during the development stage	(156,411,721)
Treasury stock, 2,000 shares at cost	(177,645)
Deferred compensation	(462,445)
Total shareholders' deficit	(31,313,490)
Total liabilities and shareholders' deficit	<u>\$ 1,729,904</u>

The accompanying notes are an integral part of these statements.

ORTEC INTERNATIONAL, INC.
(A DEVELOPMENT STAGE ENTERPRISE)
CONSOLIDATED STATEMENTS OF OPERATIONS

	Year Ended December 31,		Cumulative From March 12, 1991 (Inception) to December 31, 2005
	2005	2004	2005
Product Revenue	\$ —	\$ —	\$ 265,665
Expenses			
Product and laboratory costs	3,620,562	3,014,461	30,787,148
Personnel	3,896,068	3,857,052	41,081,555
General and administrative	1,869,106	1,664,294	20,904,457
Rent	474,013	481,782	4,446,307
Consulting	—	13,045	5,702,651
Interest expense	7,316,780	6,745,928	27,098,609
Other (income) expense	116,429	(398,662)	(2,554,218)
Loss on settlement of promissory notes	13,081,453	—	13,081,453
Lease termination costs	—	—	1,119,166
Loss on extinguishments of debt and series A preferred shares	—	—	1,004,027
	<u>30,374,411</u>	<u>15,377,900</u>	<u>142,671,155</u>
Net loss	(30,374,411)	(15,377,900)	(142,405,490)
Preferred stock dividends	(17,891)	643,904	3,011,574
Preferred stock and warrants deemed dividends and discounts	<u>5,602,657</u>	<u>1,123,000</u>	<u>10,994,657</u>
Net loss applicable to common shareholders	<u>\$(35,959,177)</u>	<u>\$(17,144,804)</u>	<u>\$(156,411,721)</u>
Net loss per share			
Basic and diluted	<u>\$ (0.93)</u>	<u>\$ (3.03)</u>	
Weighted average shares outstanding			
Basic and diluted	<u>38,534,706</u>	<u>5,655,406</u>	

The accompanying notes are an integral part of these statements.

ORTEC INTERNATIONAL, INC.
(A DEVELOPMENT STAGE ENTERPRISE)

CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY (DEFICIT)

	Common Stock		Preferred Stock			Additional	Deficit				Total
	Shares	Amount	Series B	Series C	Series D	Paid-in Capital	Accumulated During the Development Stage	Treasury Stock	Deferred Compensation	Shareholders' Equity (Deficit)	
March 12, 1991 (inception) to December 31, 1991											
Founders	155,382	\$ 155	\$ —	\$ —	\$ —	\$ 715	\$ —	\$ —	\$ —	\$ 870	
First private placement (\$3.00 per share)	21,744	22	—	—	—	64,978	—	—	—	65,000	
The Director (\$11.50 and \$53.00 per share)	14,902	15	—	—	—	249,985	—	—	—	250,000	
Second private placement (\$94.25 per share)	5,302	5	—	—	—	499,995	—	—	—	500,000	
Share issuance expense	—	—	—	—	—	(21,118)	—	—	—	(21,118)	
Net loss	—	—	—	—	—	—	(281,644)	—	—	(281,644)	
Balance at December 31, 1991	197,330	197	—	—	—	794,555	(281,644)	—	—	513,108	
Second private placement (\$94.25 per share)	2,646	3	—	—	—	250,003	—	—	—	250,006	
Second private placement (\$94.25 per share)	2,286	2	—	—	—	215,465	—	—	—	215,467	
Stock purchase agreement with the Director (\$94.25 per share)	3,182	3	—	—	—	299,995	—	—	—	299,998	
Share issuance expense	—	—	—	—	—	(35,477)	—	—	—	(35,477)	
Net loss	—	—	—	—	—	—	(785,941)	—	—	(785,941)	
Balance at December 31, 1992	205,444	205	—	—	—	1,524,541	(1,067,585)	—	—	457,161	
Third private placement (\$100.00 per share)	10,965	11	—	—	—	1,096,489	—	—	—	1,096,500	
Third private placement (\$100.00 per share)	2,250	2	—	—	—	224,998	—	—	—	225,000	
Stock purchase agreement with Home Insurance Company (\$90.00 per share)	11,112	11	—	—	—	999,988	—	—	—	999,999	
Stock purchase agreement with the Director (\$94.25 per share)	2,122	2	—	—	—	199,998	—	—	—	200,000	
Shares issued in exchange for commission	60	1	—	—	—	5,999	—	—	—	6,000	
Share issuance expenses	—	—	—	—	—	(230,207)	—	—	—	(230,207)	
Net loss	—	—	—	—	—	—	(1,445,624)	—	—	(1,445,624)	
Balance at December 31, 1993	231,953	232	—	—	—	3,821,806	(2,513,209)	—	—	1,308,829	
Fourth private placement (\$100.00 per share)	3,946	4	—	—	—	397,708	—	—	—	397,712	
Stock purchase agreement with Home Insurance Company (\$100.00 per share)	5,000	5	—	—	—	499,995	—	—	—	500,000	
Share issuance expense	—	—	—	—	—	(8,697)	—	—	—	(8,697)	
Net loss	—	—	—	—	—	—	(1,675,087)	—	—	(1,675,087)	
Balance at December 31, 1994	240,899	241	—	—	—	4,710,812	(4,188,296)	—	—	522,757	
Rent forgiveness	—	—	—	—	—	40,740	—	—	—	40,740	
Net loss	—	—	—	—	—	—	(1,022,723)	—	—	(1,022,723)	
Balance at December 31, 1995	240,899	241	—	—	—	4,751,552	(5,211,019)	—	—	(459,226)	
Initial public offering	120,000	120	—	—	—	5,999,880	—	—	—	6,000,000	
Exercise of warrants	3,389	3	—	—	—	33,882	—	—	—	33,885	
Fifth private placement (\$64.90 per share)	95,911	96	—	—	—	6,220,701	—	—	—	6,220,797	
Share issuance expenses	—	—	—	—	—	(1,580,690)	—	—	—	(1,580,690)	
Stock options issued for services ..	—	—	—	—	—	152,000	—	—	—	152,000	
Net loss	—	—	—	—	—	—	(2,649,768)	—	—	(2,649,768)	
Balance at December 31, 1996	460,199	460	—	—	—	15,577,325	(7,860,787)	—	—	7,716,998	
Exercise of warrants	115,878	116	—	—	—	10,822,675	—	—	—	10,822,791	
Share issuance expenses	—	—	—	—	—	(657,508)	—	—	—	(657,508)	
Stock options and warrants issued for services	—	—	—	—	—	660,000	—	—	—	660,000	
Net loss	—	—	—	—	—	—	(4,825,663)	—	—	(4,825,663)	
Balance at December 31, 1997 (carried forward)	576,077	\$ 576	\$ —	\$ —	\$ —	\$26,402,492	\$(12,686,450)	\$ —	\$ —	\$ 13,716,618	

The accompanying notes are an integral part of these statements.

ORTEC INTERNATIONAL, INC.
(A DEVELOPMENT STAGE ENTERPRISE)

CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY (DEFICIT)—(Continued)

	Common Stock		Preferred Stock			Additional Paid-in Capital	Deficit Accumulated During the Development Stage	Treasury Stock	Deferred Compensation	Total Shareholders' Equity (Deficit)
	Shares	Amount	Series B	Series C	Series D					
Balance at December 31, 1997 (brought forward)	576,077	\$ 576	\$ —	\$ —	\$ —	\$26,402,492	\$(12,686,450)	\$ —	\$ —	\$ 13,716,618
Exercise of warrants	22,149	22	—	—	—	1,281,935	—	—	—	1,281,957
Stock options and warrants issued for services	—	—	—	—	—	1,920,111	—	—	—	1,920,111
Sixth private placement	20,000	20	—	—	—	1,788,678	—	—	—	1,788,698
Sixth private placement—warrants issued	—	—	—	—	—	211,302	—	—	—	211,302
Share issuance expenses	—	—	—	—	—	(48,000)	—	—	—	(48,000)
Purchase of 660 shares of treasury stock (at cost)	—	—	—	—	—	—	—	(67,272)	—	(67,272)
Net loss	—	—	—	—	—	—	(8,412,655)	—	—	(8,412,655)
Balance at December 31, 1998	618,226	618	—	—	—	31,556,518	(21,099,105)	(67,272)	—	10,390,759
Exercise of warrants	1,410	1	—	—	—	14,102	—	—	—	14,103
Stock options and warrants issued for services	—	—	—	—	—	64,715	—	—	—	64,715
Seventh private placement (\$87.50 per share)	38,916	39	—	—	—	3,168,746	—	—	—	3,168,785
Seventh private placement— investor warrants	—	—	—	—	—	236,291	—	—	—	236,291
Seventh private placement— placement agent warrants	—	—	—	—	—	232,000	—	—	—	232,000
Eighth private placement (\$55.00 per share)	163,637	164	—	—	—	8,999,838	—	—	—	9,000,002
Share issuance expenses	—	—	—	—	—	(619,908)	—	—	—	(619,908)
Purchase of 910 shares of treasury stock (at cost)	—	—	—	—	—	—	—	(75,518)	—	(75,518)
Net loss	—	—	—	—	—	—	(10,040,509)	—	—	(10,040,509)
Balance at December 31, 1999	822,189	822	—	—	—	43,652,302	(31,139,614)	(142,790)	—	12,370,720
Exercise of options and warrants	17,554	17	—	—	—	327,265	—	—	—	327,282
Stock options and warrants issued for services	—	—	—	—	—	56,265	—	—	—	56,265
Ninth private placement (\$150.00 per share)	6,667	7	—	—	—	999,998	—	—	—	1,000,005
Ninth private placement— placement agent warrants	—	—	—	—	—	23,000	—	—	—	23,000
Tenth private placement (\$67.50 per share)	124,757	125	—	—	—	8,420,946	—	—	—	8,421,071
Share issuance expenses	—	—	—	—	—	(641,500)	—	—	—	(641,500)
Purchase of 430 shares of treasury stock (at cost)	—	—	—	—	—	—	—	(34,855)	—	(34,855)
Net loss	—	—	—	—	—	—	(12,129,663)	—	—	(12,129,663)
Balance at December 31, 2000	971,167	971	—	—	—	52,838,276	(43,269,277)	(177,645)	—	9,392,325
Stock options issued for services	—	—	—	—	—	188,080	—	—	—	188,080
Net loss	—	—	—	—	—	—	(15,885,377)	—	—	(15,885,377)
Balance at December 31, 2001 (carried forward)	971,167	\$ 971	\$ —	\$ —	\$ —	\$53,026,356	\$(59,154,654)	\$(177,645)	\$ —	\$ (6,304,972)

The accompanying notes are an integral part of these statements.

ORTEC INTERNATIONAL, INC.
(A DEVELOPMENT STAGE ENTERPRISE)

CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY (DEFICIT)—(Continued)

	Common Stock		Preferred Stock			Additional	Deficit			Total
	Shares	Amount	Series B	Series C	Series D	Paid-in Capital	Accumulated During the Development Stage	Treasury Stock	Deferred Compensation	Shareholders' Equity (Deficit)
Balance at December 31, 2001 (brought forward) ..	971,167	\$ 971	\$ —	\$ —	\$ —	\$53,026,356	\$ (59,154,654)	\$(177,645)	\$—	\$ (6,304,972)
Exercise of options and warrants	35,720	36	—	—	—	321	—	—	—	357
Stock options and warrants issued for services	—	—	—	—	—	113,060	—	—	—	113,060
Warrants issued with convertible debentures ..	—	—	—	—	—	440,523	—	—	—	440,523
Warrants issued with convertible redeemable preferred stock	—	—	—	—	—	559,289	—	—	—	559,289
Convertible debenture conversion benefit	—	—	—	—	—	1,042,663	—	—	—	1,042,663
Redeemable convertible preferred stock conversion benefit	—	—	—	—	—	1,097,886	—	—	—	1,097,886
Issuance of series B preferred stock (938 shares) (\$10,000 per share)	—	—	9,382,742	—	—	—	—	—	—	9,382,742
Warrants issued and exercised with preferred stock	938,275	938	(3,479,043)	—	—	3,485,443	—	—	—	7,338
Shares issuance costs— preferred stock	—	—	(866,612)	—	—	304,615	—	—	—	(561,997)
Preferred stock dividends ..	375,315	375	—	—	—	1,125,559	(1,125,934)	—	—	—
Net loss	—	—	—	—	—	—	(21,578,021)	—	—	(21,578,021)
Balance at December 31, 2002 (carried forward) ..	2,320,477	2,320	5,037,087	—	—	61,195,715	(81,858,609)	(177,645)	—	(15,801,132)
Balance at December 31, 2002 (brought forward) ..	2,320,477	2,320	5,037,087	—	—	61,195,715	(81,858,609)	(177,645)	—	(15,801,132)
Exercise of options and warrants	398,750	399	—	—	—	12,567	—	—	—	12,966
Issuance of preferred stock: series B (200 shares), series C (948 shares)	—	—	2,000,000	5,690,000	—	—	—	—	—	7,690,000
Warrants issued with preferred stock	—	—	(490,567)	(1,225,632)	—	1,716,199	—	—	—	—
Warrants issued for services	—	—	—	—	—	87,000	—	—	—	87,000
Share issuance costs— preferred stock	—	—	(393,488)	(797,327)	—	359,078	—	—	—	(831,737)
Conversion of series B preferred stock (605 shares) into common stock	2,421,556	2,422	(3,253,571)	—	—	3,251,149	—	—	—	—
Conversion of series B preferred stock into series D preferred stock (483 shares)	—	—	(2,628,602)	—	2,628,602	—	—	—	—	—
Preferred stock deemed dividends and discounts ..	—	—	—	—	—	4,269,000	(4,269,000)	—	—	—
Preferred stock dividends ..	92,308	92	—	—	—	922,985	(923,077)	—	—	—
Common stock dividend to be distributed on series C preferred stock	—	—	—	—	—	336,550	(336,550)	—	—	—
Common stock to be issued in connection with promissory notes	—	—	—	—	—	287,000	—	—	—	287,000
Adjustment for one for ten reverse stock split	74	—	—	—	—	—	—	—	—	—
Net loss	—	—	—	—	—	—	(15,920,504)	—	—	(15,920,504)
Balance at December 31, 2003 (carried forward) ..	5,233,165	\$5,233	\$ 270,859	\$ 3,667,041	\$2,628,602	\$72,437,243	\$(103,307,740)	\$(177,645)	\$—	\$(24,476,407)

The accompanying notes are an integral part of these statements.

ORTEC INTERNATIONAL, INC.
(A DEVELOPMENT STAGE ENTERPRISE)

CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY (DEFICIT)—(Continued)

	Common Stock		Preferred Stock			Additional	Deficit				Total
	Shares	Amount	Series B	Series C	Series D	Paid-in Capital	Accumulated During the Development Stage	Treasury Stock	Deferred Compensation		Shareholders' Equity (Deficit)
Balance at December 31, 2003 (brought forward)	5,233,165	\$ 5,233	\$ 270,859	\$ 3,667,041	\$ 2,628,602	\$ 72,437,243	\$(103,307,740)	\$(177,645)	\$ —		\$(24,476,407)
Common stock issued in connection with previously issued notes	157,000	157	—	—	—	(157)	—	—	—		—
Common stock issued in connection with promissory notes	331,831	332	—	—	—	745,870	—	—	—		746,202
Common stock (277,020) and 34.31 shares of series D preferred to be issued in connection with agreements which extended due date of promissory notes	—	—	—	—	—	828,540	—	—	—		828,540
Common stock issued in connection with exercise of warrants . .	32,460	32	—	—	—	293	—	—	—		325
Conversion of 35.62 shares of series C preferred stock into common stock	106,872	107	—	(137,752)	—	137,645	—	—	—		—
Payment of dividends on 35.62 shares of series C preferred stock in common stock	13,743	14	—	—	—	30,085	(30,099)	—	—		—
Common stock and series D preferred (233.83 shares) issued in connection with special warrant offer Common stock dividend to be distributed on series B and series C preferred stock	496,981	497	—	—	939,050	498,472	—	—	—		1,438,019
Option issued to director for services . .	—	—	—	—	—	613,805	(613,805)	—	—		—
Warrant issued for services	—	—	—	—	—	398,574	—	—	—		398,574
Warrant issued in connection with lease	—	—	—	—	—	94,393	—	—	—		94,393
Share issuance expenses	—	—	—	—	—	18,500	—	—	—		18,500
Special warrant offer deemed dividends	—	—	—	—	—	(26,600)	—	—	—		(26,600)
Net loss	—	—	—	—	—	1,123,000	(1,123,000)	—	—		—
	—	—	—	—	—	—	(15,377,900)	—	—		(15,377,900)
Balance at December 31, 2004 (carried forward)	6,372,052	\$ 6,372	\$ 270,859	\$ 3,529,289	\$ 3,567,652	\$ 76,899,663	\$(120,452,544)	\$(177,645)	\$ —		\$(36,356,354)

The accompanying notes are an integral part of these statements.

ORTEC INTERNATIONAL, INC.
(A DEVELOPMENT STAGE ENTERPRISE)

CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY (DEFICIT)—(Continued)

	Common Stock		Preferred Stock			Additional	Deficit			Total
	Shares	Amount	Series B	Series C	Series D	Paid-in Capital	Accumulated During the Development Stage	Treasury Stock	Deferred Compensation	Shareholders' Equity (Deficit)
Balance at December 31, 2004 (brought forward)	6,372,052	\$ 6,372	\$ 270,859	\$ 3,529,289	\$ 3,567,652	\$ 76,899,663	\$(120,452,544)	\$(177,645)	\$ —	\$(36,356,354)
Common stock and series D preferred (34.31 shares) issued in connection with agreements which extended due date of promissory notes	277,020	277	—	—	274,500	(274,777)	—	—	—	—
January 2005 Private Placement: Common stock issued in connection with private placement	6,483,962	6,484	—	—	—	4,769,616	—	—	—	4,776,100
Common stock and series D preferred (1,720.16 shares) issued in connection with promissory note conversion	7,953,123	7,953	—	—	5,733,853	14,887,606	—	—	—	20,629,412
Common stock and series D preferred (1,086.21 shares) issued in connection with Series C preferred exchange	3,283,682	3,284	—	(3,529,289)	3,620,702	2,011,770	(2,106,467)	—	—	—
Common stock issued in connection with exercise of additional investment right from private placement	153,263	153	—	—	—	114,794	—	—	—	114,947
Common stock issued in connection with February 2005 private placement	120,000	120	—	—	—	86,153	—	—	—	86,273
Common stock issued in connection with exchange for series B preferred stock	220,647	221	(270,859)	—	—	272,254	(1,616)	—	—	—
Common stock issued to officers	1,645,000	1,645	—	—	—	749,939	—	—	(462,445)	289,139
Common stock issued upon exercise of warrants	3,658,513	3,659	—	—	—	—	—	—	—	3,659
October 2005 Private Placement: Common stock issued Common stock and Series D preferred (2,714.62 shares) and warrants issued for promissory notes	14,590,764	14,591	—	—	—	3,159,025	—	—	—	3,173,616
Modifications of Series E warrant prices	—	—	—	—	—	3,490,140	(3,476,683)	—	—	13,457
Warrant issued for services	—	—	—	—	—	7,189	—	—	—	7,189
Share issuance expenses Net loss	—	—	—	—	—	(14,234)	—	—	—	(14,234)
							(30,374,411)			(30,374,411)
Balance at December 31, 2005	<u>51,104,951</u>	<u>\$51,106</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$15,911,331</u>	<u>\$109,775,884</u>	<u>\$(156,411,721)</u>	<u>\$(177,645)</u>	<u>\$(462,445)</u>	<u>\$(31,313,490)</u>

The accompanying notes are an integral part of these statements.

ORTEC INTERNATIONAL, INC.
(A DEVELOPMENT STAGE ENTERPRISE)
CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year Ended December 31,		Cumulative From March 12, 1991 (Inception) to December 31, 2005
	2005	2004	2005
Cash flows from operating activities			
Net loss	\$(30,374,411)	\$(15,377,900)	\$(142,405,490)
Adjustments to reconcile net loss to net cash used in operating activities			
Depreciation and amortization	291,975	466,966	5,566,847
Allowance for doubtful accounts	—	—	5,374
Unrealized loss on marketable securities	—	—	11,404
Realized loss on marketable securities	—	—	5,250
(Gain)/loss on sale of property and equipment	—	(26,802)	(58,642)
Loss on settlement of promissory notes	13,081,453	—	13,081,453
Cost to terminate lease on New Jersey facility	—	—	836,032
Non-cash stock compensation	289,139	94,000	3,624,370
Non cash interest	126,391	1,856,832	1,983,223
Non-cash imputed interest	6,830,890	4,184,254	22,922,150
Non-cash production suite charges	235,500	—	235,500
Gain on loan adjustment	—	(236,000)	(236,000)
Loss on extinguishments of debt & series A preferred stock	—	—	1,004,027
Purchase of marketable securities	—	—	(19,075,122)
Sales of marketable securities	—	—	19,130,920
Other	20,646	—	20,646
Change in operating assets and liabilities			
Other current assets and other assets	(23,036)	(96,665)	(61,090)
Accounts payable and accrued liabilities	(1,129,595)	1,298,208	5,047,362
Net cash used in operating activities	(10,651,048)	(7,837,107)	(88,361,786)
Cash flow from investing activities			
Purchases of property and equipment	(66,535)	(81,622)	(4,613,877)
Proceeds from sale of property and equipment	—	14,025	145,926
Payments for patent applications	(49,167)	(48,975)	(1,069,873)
Organization costs	—	—	(10,238)
(Security deposit) Security deposits refunded	16,000	—	(790,273)
Purchases of marketable securities	—	—	(594,986)
Sale of marketable securities	—	—	522,532
Net cash used in investing activities	(99,702)	(116,572)	(6,410,789)
Cash flows from financing activities			
Proceeds from issuance of notes payable	3,486,000	6,506,626	13,648,126
Proceeds from issuance of common stock	8,150,936	—	61,701,458
Proceeds from exercise of warrants	3,659	1,338,344	1,362,663
Proceeds from insurance premium financing	220,000	280,000	500,000
Share issuance expenses and other financing costs	(14,234)	(26,600)	(5,384,247)
Purchase of treasury stock	—	—	(177,645)
Proceeds from issuance of loan payable	—	—	1,446,229
Proceeds from obligation under revenue interest assignment	—	—	10,000,000
Proceeds from issuance of convertible debentures	—	—	5,908,000
Proceeds from issuance of preferred stock—			
Series A	—	—	1,200,000
Series B	—	—	3,070,000
Series C	—	—	5,690,000
Advances received	—	—	130,000
Repayment of insurance premium financing	(220,000)	(280,000)	(500,000)
Repayment of capital lease obligations	(66,065)	(154,079)	(584,794)
Repayment of loan payable	(203,462)	(173,943)	(1,239,161)
Repayment of obligation under revenue interest assignment	—	—	(11,414)
Repayment of notes payable	—	—	(515,500)
Repayment of promissory notes	(158,065)	(637,686)	(795,751)
Net cash provided by financing activities	11,198,769	6,852,662	95,447,964
Net Increase/(Decrease) in Cash And Cash Equivalents	448,019	(1,101,017)	675,389
CASH AND CASH EQUIVALENTS:			
Beginning of year	227,370	1,328,387	—
End of year	\$ 675,389	\$ 227,370	\$ 675,389

The accompanying notes are an integral part of these statements.

ORTEC INTERNATIONAL, INC.
(A DEVELOPMENT STAGE ENTERPRISE)
CONSOLIDATED STATEMENTS OF CASH FLOWS—(Continued)

	<u>Year Ended December 31,</u>		<u>Cumulative</u>
	<u>2005</u>	<u>2004</u>	<u>From</u>
			<u>March 12, 1991</u>
			<u>(Inception) to</u>
			<u>December 31,</u>
			<u>2005</u>
Supplemental disclosures of cash flow information:			
Non-cash financing and investing activities			
Capital lease obligations	\$ 7,717	\$ 52,462	\$ 628,523
Deferred offering costs included in accrued professional fees	—	—	314,697
Financings costs—other long-term obligations	—	—	59,500
Forgiveness of rent payable	—	—	40,740
Share issuance expenses—warrants	—	—	255,000
Deferred compensation	751,584	—	751,584
Dividends on preferred stock paid in common shares—			
Series B	—	50,000	2,099,011
Series C	(17,891)	593,904	576,013
Accretion of discount on preferred stock and warrants	5,602,657	1,123,000	10,994,657
Series B preferred stock converted to common stock	270,859	—	270,659
Series C preferred stock exchanged for common stock	3,529,289	—	3,529,289
Issuance of Series D preferred stock in lieu of common stock	12,343,679	—	12,343,679
Share issuance expenses for preferred stock incurred through issuance of warrants—			
Series B	—	—	391,307
Series C	—	—	272,386
Share issuance of series D preferred stock in exchange from series B preferred stock	—	—	2,628,602
Promissory notes repaid with common stock	13,112,626	—	13,112,626
Promissory note interest paid in common stock	658,776	—	658,776
Promissory notes forgiven for warrant participation	—	100,000	100,000
Warrant issued in connection with lease	—	18,500	18,500
Conversion of series C preferred stock into common stock	—	137,645	137,645
Contribution of capital of amount due to founder	—	398,967	398,967
Equipment transferred in satisfaction of deposit	—	25,000	100,000
Discount on promissory notes	—	746,202	1,033,202
Accounts payable converted to promissory notes	—	837,468	837,468
Advances converted to promissory notes	—	130,000	130,000
Cash paid for interest	\$ 142,770	\$ 69,975	\$ 860,626
Cash paid for income taxes	\$ —	\$ 2,835	\$ 203,411

The accompanying notes are an integral part of these statements.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1 - FORMATION OF THE COMPANY AND BASIS OF PRESENTATION

Formation of the Company

Ortec International, Inc. ("Ortec" or the "Company") was incorporated in March 1991 as a Delaware corporation to secure and provide funds for the further development of the technology developed by Dr. Mark Eisenberg of Sydney, Australia, to replicate in the laboratory, a tissue engineered skin substitute for use in skin regeneration procedures (the "Technology"). Pursuant to a license agreement dated September 7, 1991, Dr. Eisenberg had granted us a license for a term of ten years, with automatic renewals by us for two additional ten-year periods, to commercially use and exploit the Technology for the development of products. In April 1998, Dr. Eisenberg assigned his patent for the Technology to us.

The Skin Group, Ltd. (the "Skin Group") also was formed as a Delaware corporation in March 1991, to raise funds for the development of the Technology. On July 27, 1992, the Skin Group was merged with and into Ortec. Owners of Skin Group shares were given .83672 of an Ortec share for each Skin Group share. The merger was accounted for as if it were a pooling of interests and, accordingly, the accompanying financial statements include the accounts of the Skin Group for all periods presented.

Basis of Presentation

We are a development stage enterprise which had no operating revenue prior to December 2001. During 2001, we received Food and Drug Administration (FDA) approval for the use of the fresh form of OrCel® (ORCEL) for the treatment of patients with recessive dystrophic epidermolysis bullosa and for donor sites in burn patients. We then began marketing and selling our product for use on patients with those medical conditions. Revenues were not significant. We terminated our selling efforts and elected to focus our efforts on developing a cryopreserved form of our product for treating medical conditions with considerably larger patient populations. Venous stasis ulcers is a medical condition with a larger patient population. We completed a clinical trial during 2003 for the use of a cryopreserved form of ORCEL to treat venous stasis ulcers. In February 2004, we filed an application with the FDA for pre-market approval (PMA). On April 25, 2005 the FDA advised us that we had to have additional clinical data from a confirmatory clinical trial to demonstrate reasonable assurance of safety and effectiveness of ORCEL in treating patients with venous stasis ulcers. In late June 2005, the FDA approved our conducting a 60 patient confirmatory clinical trial. We obtained FDA approval for the trial protocol in mid July 2005 and began the confirmatory clinical trial in mid August 2005. Our plan of operation for the next twelve months is to complete such clinical trial and continue to work towards obtaining regulatory clearance for commercial sales of cryopreserved ORCEL to treat venous stasis ulcers. In the interim, we are working with Cambrex Bio Science Walkersville, Inc., a subsidiary of Cambrex Corporation (Cambrex) to limit our expenditures under our manufacturing agreement with Cambrex primarily to those which are essential for conducting the clinical trial.

The accompanying financial statements have been prepared assuming that we will continue as a going concern. We incurred a net loss applicable to common shareholders of \$36 million during the year ended December 31, 2005, and, as of that date, our current liabilities exceeded our current assets by \$32.2 million, our total liabilities exceeded our total assets by \$31.3 million and we have a deficit accumulated in the development stage of \$156.4 million. These factors, among others, raise substantial doubt about our ability to continue as a going concern.

During 2005 we raised gross proceeds of \$9.3 million through private placements of our common stock and approximately \$3.5 million from a convertible note offering. Additionally we converted \$13.1 million of promissory notes and \$773,000 of accrued interest into, and all of the outstanding shares of our Series B and C preferred stock were exchanged by the holders for, our common stock.

We expect to incur obligations of approximately \$850,000 per month primarily for personnel and rent; insurance, fees to Cambrex for a production suite and technology transfer activities, various research and development activities, and payment of past due obligations. We will require substantial funding to enable us to continue our research and development activities, pay a portion of our past due obligations, complete the additional clinical trial necessary to obtain PMA for our ORCEL to treat venous stasis ulcers, and provide for our general and corporate working capital requirements for 2006.

As of December 31, 2005, payment of approximately \$1,354,000 of the approximately \$1,980,000 we owed to our trade creditors was past due. We have entered into agreements with creditors to whom we owe an aggregate of \$736,000 (as of December 31, 2005) to pay \$471,000 in 2006 and \$265,000 in 2007.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

While we have arranged for payment of some of our obligations over a period of time, and have to make other payments of past due obligations to our current and ongoing suppliers, our ability to make payments we have agreed to pay and to insure continued receipt of needed supplies, and to continue reducing our past due obligations, will depend on our ability to secure needed financing or our ability to issue equity in satisfaction of certain obligations.

We hope to obtain additional funds through the sale of our securities to the public and through private placements, debt financing or other short-term loans. We may not be able to secure any financing nor may we be able to reach the larger patient population markets of persons with venous stasis ulcers and diabetic foot ulcers, with funds that we may be able to raise. We are also likely to continue to encounter difficulties which are common to development stage companies, including unanticipated costs relating to development, delays in the testing of products, regulatory approval and compliance and competition.

Our capital funding requirements depend on numerous factors, including:

- the progress and magnitude of our research and development programs;
- the time involved in obtaining regulatory approvals for the commercial sale of our ORCEL product in its cryopreserved form to treat venous stasis ulcers and, later, diabetic foot ulcers;
- the costs involved in filing and maintaining patent claims;
- technological advances;
- competitive and market conditions;
- the successful implementation of the agreements we have entered into with Cambrex for manufacturing and sales of our ORCEL product;
- our ability to establish and maintain other collaborative arrangements and
- the cost and effectiveness of commercialization activities and arrangements.

We believe that our cash and cash equivalents on hand at December 31, 2005, approximately \$675,000, as well as the additional funds we will need to raise in 2006, may enable us to continue our operations for the next twelve months. There can be no assurances that we can raise additional funds. See Note 18 regarding funding made subsequent to December 31, 2005.

These financial statements have been prepared assuming that we will continue as a going concern. Successful future operations depend upon the successful development and marketing of our ORCEL product. Historically we have funded our operating losses by periodically raising additional sources of capital. If additional funding is not available to us when needed, we may not be able to continue operations. No adjustments have been made to the accompanying financials as a result of this uncertainty.

Principles of Consolidation

The consolidated financial statements include the accounts of the Company and its wholly owned subsidiary. All intercompany balances and transactions have been eliminated.

Common Stock Reserve Split

On June 24, 2003, we effected a reverse stock split of our common shares outstanding, whereby every stockholder, warrant and option holder, was granted one new common share or warrant or option to purchase common shares, for every ten outstanding common shares (or its equivalent). The par value of the common shares remained unchanged at \$.001 per share. The exercise prices of all warrants and options outstanding were adjusted as a result of this reverse split. The conversion rates of the preferred stock outstanding were also adjusted.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

2 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Revenue Recognition

Product revenue is recognized upon shipment of ORCEL when title and risk of loss pass to the customer, which occurs when the end user customer receives the product. Royalties from licensees will be based on third-party sales of licensed products and will be recorded in accordance with contract terms when third-party results are reliably measurable and collectibility is reasonably assured. Fees paid to us upon entering a license agreement are recognized when earned as defined by the terms of the agreement.

In accordance with EITF Issue No. 00-21, *Revenue Arrangements with Multiple Deliverables*, we review each contract to determine if there are multiple revenue-generating activities that constitute more than one unit of accounting. Revenue is recognized for each unit of accounting based on revenue recognition criteria relevant to that unit. Up-front payments are deferred, if appropriate, and recognized into revenues over the obligation period.

Research and Development Costs

We are in the business of research and development and therefore, all research and development costs, including payments relating to products under development, research, consulting agreements and personnel costs, are expensed when incurred. Research and Development costs aggregated \$7,535,532 and \$7,139,733, for the years ending 2005 and 2004, respectively. Research and Development costs are comprised of production and laboratory costs, rent, consulting, personnel, and depreciation and amortization expenses.

Depreciation and Amortization

Property and equipment are carried at cost, less any grants received for construction. In 1996, we received a \$400,000 grant toward the construction of our new laboratory and office facilities and we received an additional grant of \$130,000 in 1998.

Office furniture and equipment and laboratory equipment are depreciated on the straight-line basis over the estimated lives of the assets (5 years). Leasehold improvements are amortized over the shorter of the term of the related lease or the life of the asset.

Intangible Assets

Our intangible assets consist of patent application costs. We amortize these separately identifiable assets over their estimated useful lives. Patent application costs relate to our U.S. patent application and application fees in foreign jurisdictions and consist of legal and other direct fees. The recoverability of the patent application costs is dependent upon, among other matters, obtaining further FDA approvals for the use of the underlying technology.

Impairment of Long-Lived Assets

We review long-lived assets, which consist of fixed assets and patent application costs, for possible impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. We have determined, based on estimated future cash flows, that no provision is necessary for the impairment of long-lived assets at December 31, 2005.

Foreign Currency Translation

We conducted some of our research and development at our laboratory in Sidney, Australia. However, because all Australian expenditures were funded from the United States, we determined that the functional currency of our Australian office was the U.S. dollar. Accordingly, current assets and current liabilities are remeasured into the functional currency using current exchange rates and non-current assets and liabilities are remeasured using historical exchange rates. Expense accounts are measured using the average rate in effect for the year. As of December 31, 2002, we terminated all of our research and development activities at our laboratory in Sidney.

NOTES TO-CONSOLIDATED FINANCIAL STATEMENTS

Use of Estimates

In preparing financial statements in conformity with accounting principles generally accepted in the United States of America, management is required to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Income Taxes

Deferred tax assets and liabilities are recognized for the estimated future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates in effect for the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. A valuation allowance is provided for as it is more likely than not that the deferred tax assets will not be realized.

Cash and Cash Equivalents

For purposes of the statement of cash flows, we consider all highly liquid debt instruments purchased with original maturities of three months or less to be cash equivalents. Cash equivalents consist principally of money market funds. The fair value of cash and cash equivalents approximates the recorded amount because of the short-term maturity of such instruments.

Net Loss Per Share

Net loss per common share is based on the weighted-average number of common shares outstanding during the periods.

Basic net loss per share is computed by dividing the net loss by the weighted-average common shares outstanding for the period. Diluted net loss per share reflects the weighted-average common shares outstanding plus the potential dilutive effect of securities or contracts which are convertible to common shares, such as options, warrants and convertible preferred stock.

Options and warrants to purchase shares of common stock were not included in the computation of diluted net loss per share in each of the years presented because to do so would have been antidilutive for the periods presented.

The amount of options and warrants excluded are as follows:

	Year ended December 31;	
	2005	2004
Warrants	41,949,135	988,603
Stock Options – in plan	434,542	428,324
Stock Options – outside of plan	7,733,638	1,374,400

Additionally, the effects of conversion of the preferred stock were excluded from the weighted average share calculation, as the effect would be antidilutive. An aggregate of 25,088,062 and 5,804,977 shares of common stock would be issuable upon conversion of the preferred stock outstanding at December 31, 2005 and December 31, 2004, respectively.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Employee Stock Option Plan

We account for our employee stock options under the recognition and measurement principles of APB Opinion No. 25 (APB 25), Accounting for Stock Issued to Employees, and related Interpretations. No stock-based employee compensation cost is reflected in net income, as all options granted under these plans had an exercise price equal to the market value of the underlying common stock on the date of grant.

The following table illustrates the effect on net income and earnings per share if we had applied the fair value recognition provisions of FASB Statement (SFAS) No.123, "Accounting for Stock-Based Compensation".

	Year ended December 31,	
	2005	2004
Net loss applicable to common shareholders, as reported	\$ (35,959,177)	\$ (17,144,804)
Deduct: Total stock-based employee compensation income (expense) determined under fair value based method	(1,143,889)	425,801
Pro forma net loss	<u>\$ (37,103,066)</u>	<u>\$ (16,719,003)</u>
Net loss applicable to common shareholders per share:		
Basic and Diluted – as reported	\$ (0.93)	\$ (3.03)
Basic and Diluted – pro forma	\$ (0.96)	\$ (2.96)

We utilized the Black-Scholes option-pricing model to quantify the expense of options and warrants granted to non-employees and the pro forma effects on net loss and net loss per share of the fair value of the options and warrants granted to employees during the years ended December 31, 2005 and 2004. The following weighted average assumptions were made in estimating fair value.

	Years ended December 31,	
	2005	2004
Risk-free interest rate	4.2 %	3.1 %
Expected option life	3.8 years	5 years
Expected volatility	85.9 %	80.9 %

The weighted average fair value at the date of grant for options granted during the year ended December 31, 2005 and 2004 was \$0.33 and \$1.92, respectively.

Effect of New Accounting Standards

In December 2004, the FASB issued SFAS No. 123(R), "Share-Based Payment" which establishes accounting standards for all transactions in which an entity exchanges its equity instruments for goods and services. This statement is a revision to SFAS No. 123, "Accounting for Stock-Based Compensation", supersedes APB 25 and amends SFAS No. 95, "Statement of Cash Flows." SFAS No. 123(R) eliminates the ability to account for share-based compensation using the intrinsic value method allowed under APB 25 and will require us to recognize share-based compensation as compensation expense in the statement of operations based on the fair values of such equity on the date of the grant, with the compensation expense recognized over the period in which the recipient is required to provide service in exchange for the equity award. This statement will also require us to adopt a fair value-based method for measuring the compensation expense related to share-based compensation. SFAS No. 123(R) must be adopted no later than periods beginning after December 15, 2005 and we will adopt SFAS No. 123(R) on January 1, 2006. We believe the adoption of SFAS No. 123(R) will have a material impact on our results of operations and earnings per share.

3 - CONCENTRATION OF CREDIT RISK

We maintain cash and money market accounts primarily at two financial institutions located in New York City. The FDIC insures cash accounts for amounts up to \$100,000. At times, our balances exceed such FDIC limits. We have not experienced any losses in such accounts.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

4 - PROPERTY AND EQUIPMENT

Property and equipment consist of the following at December 31, 2005:

Laboratory equipment	\$ 1,769,967
Office furniture and equipment	1,118,481
Leasehold improvements	<u>1,372,097</u>
	4,260,545
Accumulated depreciation and amortization	<u>4,062,214</u>
	<u>\$ 198,331</u>

Depreciation and amortization expense for the years ended December 31, 2005 and 2004 was approximately \$203,000 and \$385,000, respectively.

As of December 31, 2005 and 2004, included above was \$543,000 and \$535,000 in equipment purchased under capital leases and \$519,000 and \$460,000 in accumulated amortization, respectively.

5 - PATENTS

Patent application costs are stated at cost less amortization computed by the straight-line method over the useful life of the patent. As of December 31, 2005, patents, net of accumulated amortization, were as follows:

Patents subject to Amortization	Expiration Date	
Composite Culture Skin (CCS)	2/1/2011	\$ 959,857
Manufacturing of Bi-layered Collagen Sponge	12/28/2020	33,037
Cryopreservation Process	12/26/2021	<u>78,759</u>
		1,071,653
Accumulated amortization		<u>524,318</u>
		<u>\$ 547,335</u>

Amortization expense for the years ended December 31, 2005 and 2004, was \$89,000 and \$82,000, respectively. The estimated annual amortization expense expected, based on current intangible balances, for the years 2006 through 2009 is \$93,000 per year.

Our U.S. patent for CCS was issued in 1994. During 2002 and 2003 we were issued two patents by the United States Patent Office. The first patent covers unique manufacturing processes for our tissue-engineered product, ORCEL. These processes specifically relate to the manufacturing of our bi-layered collagen sponge structure and when implemented, can reduce the current manufacturing costs of ORCEL. This patent was issued on December 31, 2002. The second patent covers the freezing process for ORCEL. This process, referred to as cryopreservation, gives our product a minimum shelf life of seven months, as opposed to only a few days when our product is not cryopreserved. This second patent was issued on October 28, 2003.

There can be no assurance that any patent will provide commercial benefits to us. We have determined that no provision for impairment is necessary at December 31, 2005.

We have granted a security interest in our United States and Canadian patents and trademarks relating to ORCEL to collateralize payments we will be required to make to satisfy our obligation under a Revenue Interest Assignment Agreement (see Note 10).

ORTEC INTERNATIONAL, INC.
(A DEVELOPMENT STAGE ENTERPRISE)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

6 - ACCOUNTS PAYABLE AND ACCRUED EXPENSES

Accounts payable and accrued expenses consist of the following at December 31, 2005:

Accounts payable	\$ 1,980,425
Accrued compensation	591,082
Accrued professional fees	570,800
Accrued expenses	167,016
Deferred income	50,000
	<u>\$ 3,359,323</u>

7 - LEASES

In March 1996, we entered into a five-year lease with Columbia University for our laboratory and offices in Columbia's Audubon Biomedical Science and Technology Park in New York City. Construction of the laboratory and office facility was completed in July 1996 and became fully operational in November 1996. We utilize our laboratory facilities to produce ORCEL for research and development activities including cell expansion and biomaterial research. On December 18, 2003, we amended the lease agreement with Columbia University, extending the lease term to December 2005. With this amendment, we agreed to pay Columbia \$25,588 a month for past due rent commencing on February 1, 2004 and ending on December 31, 2005. In March 2006 we signed the Third Lease Amendment which extended the existing lease until December 31, 2007. See Note 18.

On August 5, 2002, we reached an agreement with the New Jersey Economic Development Authority (NJEDA) to terminate a 2001 lease and to enter into a new lease covering production and office space. Monthly payments under such lease began on January 1, 2003. On June 9, 2003 NJEDA and we executed an agreement to terminate this lease. Based on the terms of this settlement, a termination cost of \$978,000 was agreed upon. This termination costs was settled by applying the \$623,000 security deposit, plus accrued interest thereon, with the balance of \$340,000 paid on June 11, 2003. In 2003, we recorded a lease termination cost of \$1,119,166 consisting of the aforementioned \$978,000 together with \$141,166 of other costs that we incurred in connection with the build-out of the leasehold. We continued to rent space in North Brunswick, New Jersey pursuant to a lease until its expiration on July 31, 2004, at a rent of \$2,300 per month.

Future minimum lease payments under a noncancellable operating lease primarily for office and laboratory space and the present value of future minimum lease payments under capital leases as of December 31, 2005 are as follows:

Year ending December 31,	Leases	
	Operating	Capital
2006	\$ 730,320	\$ 23,525
2007	730,320	8,694
2008		2,188
Total	<u>\$ 1,460,640</u>	<u>34,407</u>
Less amounts representing interest		11,053
Present value of net minimum capital lease payments		23,354
Less: current portion		13,405
Long-term portion		<u>\$ 9,949</u>

In connection with a lease agreement dated February 27, 2004, we issued a two-year warrant to purchase 14,052 shares of our common stock at \$3.25 per share. We valued the warrant utilizing a Black-Scholes valuation model at \$18,500. On November 2, 2004 the Board of Directors approved the issuance of the aforementioned warrant.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

8 - NOTES PAYABLE

Promissory notes at December 31, 2005 consists of:

Promissory notes - CUH2A, 4%, due through February 2008	91,717
Current portion	41,635
Noncurrent portion	<u>\$ 50,082</u>

The CUH2A promissory note was a structured payout of a previous vendor obligation. We pay them \$3,712 monthly.

Minimum payments to be made under the terms of the promissory notes are as follows:

Year ending December 31,	
2006	\$ 44,546
2007	44,546
2008	<u>6,783</u>
	95,875
Less amount representing interest	<u>4,158</u>
Net present value of future loan payments	<u>\$ 91,717</u>

On February 2, 2005, we entered into a commercial premium finance agreement with First Insurance Funding Corp. of New York in the amount of \$220,000. The financing agreement bore interest at 7.23% and required nine monthly payments of \$25,187 beginning March 2005. The financing was utilized to fund the premium payments for our directors and officers insurance policy and has been repaid as of December 31, 2005.

9 - OBLIGATION UNDER REVENUE INTEREST ASSIGNMENTS

On August 29, 2001, as amended February 2003, we entered into a Revenue Interest Assignment Agreement with Paul Royalty Fund L.P. (PRF), which terminates on December 31, 2011. Under such agreement we were eligible to receive \$10,000,000 during 2001. We received \$6,000,000 during 2001 and the remaining \$4,000,000 in January 2002.

In February 2003, PRF and the Company signed an amendment to the agreement, restating and updating certain provisions of the original agreement, including removing requirements for additional funding to be provided by PRF. In connection therewith, PRF purchased 50 shares of our Series B convertible preferred stock investing \$500,000, and for which we issued to PRF 73,077 shares of our common stock and granted PRF warrants to purchase an aggregate of 50,000 shares of our common stock, at exercise prices of \$15.00 per share for 25,000 shares and at \$20.00 per share for the other 25,000 shares. The February 2003 amendments to our agreements with PRF provided, among other things, for (a) the election of one director designated by PRF, (b) the right of one observer (other than such director) selected by PRF to attend and observe all meetings of our Board of Directors and (c) for us to use our best efforts to have independent directors who are acceptable to both us and PRF, including a director designated by PRF, as a majority of our Board of Directors.

In consideration for the \$10,000,000, PRF will receive a minimum of 3.33% of the first \$100,000,000 of annual sales plus 1.99% of annual sales in excess of \$100,000,000 of ORCEL in the United States, Canada and Mexico. Such percentage may be further adjusted upward or downward, based on the volume of net sales to end users of our products in those three countries. Beginning on January 1, 2003, PRF was entitled to receive each year the first proceeds to us from end user sales of our products in North America. The annual amounts that PRF will be able to draw in advance against the end user sales of our products are \$7,500,000 in 2005 through 2011. The agreement provides for quarterly and annual accountings between PRF and us for those advance payments. The purpose of these accountings is to reconcile the advances paid against the actual amount we are required to pay computed on the basis of the aforementioned percentages of sales volume. Based on this reconciliation of the actual calculated amounts versus the advances paid, we will either be required to pay additional amounts or receive a refund of all or a portion of the advances we paid to PRF. We have not paid PRF any advances, as there were no sales during 2003, 2004 and 2005. The amounts received from PRF have been classified as debt

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

in accordance with our interpretation of Emerging Issues Task Force (EITF) Issues No. 88-18, "Sales of Future Revenue". PRF bears the risk of revenue interest paid being significantly less than the current revenue interest obligation, as well as the reward of revenue interest paid to it being significantly greater than the current revenue interest obligation. Therefore we are under no obligation to make any other payments to PRF in the scenario when no repurchase right (as defined) is triggered and no significant interest payments are made. Conversely, we will be obligated to continue to make revenue interest payments in the scenario where sales are sufficiently high to result in amounts due under the Revenue Interest Assignment Agreement being in excess of the current revenue interest obligation.

We granted PRF a security interest in our United States and Canadian patents and trademarks relating to our technology for our ORCEL product (collectively, the "Pledged Assets"), to secure payments required to be made by us to PRF under this agreement. Pursuant to the default provisions under the agreement PRF may require us to repurchase their revenue interest at the put option exercise price which is defined as a price which would yield an internal rate of return to PRF of 30%.

The events that could require us to repurchase our revenue interest include:

- any change of control of our company;
- a transfer of substantially all of our assets;
- a transfer of our interests in our products;
- a judicial decision that has a material adverse effect on our business, operations, assets, or financial condition;
- the occurrence of any event that has a material adverse effect on our ability to perform our obligations to repurchase the revenue interest obligation;
- the acceleration of our obligations or the exercise of default remedies by a secured lender under certain debt instruments; a funding termination event (as defined) such as a bankruptcy event (as defined);
- our insolvency (as defined);
- the breach of representations, warranties or certifications made by us in the agreements with PRF that, individually or in the aggregate, would reasonably be expected to have a material adverse effect on our business, operations, assets or financial condition, and such breach is not cured within 30 days after notice thereof from PRF.

Additionally we agreed not to issue any new debt or equity securities that contain mandatory cash dividend or redemption provisions through the revenue interest period, or December 31, 2011.

On December 13, 2004 PRF entered into a forbearance agreement with us agreeing that they cannot exercise their right to compel us to repurchase their interest in our revenues because of our insolvency prior to July 1, 2006 (which is defined as (a) our liabilities, excluding our revenue interest assignment obligation, exceeding the fair market value of our assets or (b) our inability to pay our debts as they become due).

As defined in our agreement with PRF we are currently insolvent. As a result of this insolvency our obligation under the revenue interest assignment is stated at \$29,569,000, the amount PRF could compel us to repurchase their interest in our revenues at December 31, 2005, had they not entered into a forbearance agreement with us. This amount represents the amount that would give PRF a 30% internal rate of return on their \$10,000,000 from the dates of their original investments. Should we continue to be insolvent we will need to continue to incur non-cash interest charges for this obligation. At such time when the default provisions are no longer applicable, the effective interest rate imputed on the obligation will be determined using the interest method and payments to PRF will be recorded as a reduction of our obligation under the revenue interest assignment.

In accordance with accounting promulgated by Statements of Financial Accounting Standards No. 15, "Accounting by Debtors and Creditors for Troubled Debt Restructurings" (SFAS 15) even if we are no longer insolvent as long as our future cash payments relating to the revenue interest assignment obligation are indeterminate, the revenue interest assignment obligation would remain at the value that achieves the 30% internal rate of return for PRF through the last date of our insolvency. However, we would no longer have to accrue any additional interest to achieve a 30% internal rate of return related to insolvency. That is, we would not reverse the accrual for the insolvency repurchase event even when we are no longer insolvent. At December 31, 2005 the amount attributed to the insolvency is \$19,569,000. Our revenue stream is considered indeterminate since we cannot predict with certainty the payments we will be required to make on this obligation since theoretically our sales are not limited in amount and payments under our agreement with PRF are determined based on future sales. We estimate that we would need to achieve a North American sales level of

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

approximately \$1,160,000,000 over the approximate remaining five sales years under the agreement to offset the principal balance of the \$29,569,000 revenue interest obligation.

SFAS 15 allows debtors that can predict with certainty the absolute amounts of future cash flow payments to record an immediate gain if the maximum future cash payments are less than the carrying amount of the obligation. In the case where the future cash payments are indeterminate, as ours are considered, the gain is not recognized until the end of the term of the outstanding debt, December 31, 2011, or upon termination. As such, we believe we will likely record a gain on the revenue interest assignment obligation to PRF in 2011 or upon termination, if sooner.

If we were unable to repurchase the revenue interest upon a repurchase event, PRF could foreclose on the Pledged Assets, and we could be forced into bankruptcy. PRF can also foreclose on the Pledged Assets if we remain insolvent (waived until July 1, 2006) or are involved in a voluntary or involuntary bankruptcy proceeding. No repurchase events or foreclosures have occurred as of December 31, 2005.

We also have the option to repurchase PRF's interest upon the occurrence of a change in control of the Company or a complete divestiture by us of our interests in our products, for an amount of cash flows that will generate a 35% internal rate of return to PRF.

On December 16, 2004, pursuant to a Special Warrant Offer which reduced the exercise prices of a portion of the 50,000 warrants that PRF received in February 2003 to \$1.00 in exchange for the surrender of the balance, warrants to purchase 27,778 shares of our common stock were exercised for which we received \$27,889, and warrants to purchase 22,222 shares of our common stock were surrendered to us. As a result of the Special Warrant Offer PRF was considered to have received a deemed dividend of approximately \$2,500 based on a Black Scholes calculation considering the valuation of the warrants prior to the December 16, 2004 offering and subsequent to the offering (see Note 10).

10 - EQUITY TRANSACTIONS

Each share of our common stock is entitled to one vote.

In September 2001, we, with shareholder approval, increased the authorized amount of our common stock to 35,000,000 shares and authorized the issuance of up to 1,000,000 shares of preferred stock.

In February 2003, we, with shareholder approval, increased the authorized amount of our common stock to 200,000,000 shares.

On June 24, 2003, we effected a one for ten reverse stock split for each outstanding share of common stock. This reverse stock split was retroactively reflected in the accompanying financial statements and all references to shares are to the new shares with per share amounts appropriately adjusted.

Founders: Pursuant to an agreement between Dr. Eisenberg and the other founders (the "Other Founders"), a business relationship was formed by the founders for the manufacture and sale of products derived from the Technology (the "Business Agreement"). Under the terms of the Business Agreement, Dr. Eisenberg, who was the owner of all the capital stock of Ortec (60,000 shares) agreed to license the Technology to Ortec and sell 70% of Ortec's shares for a purchase price of \$1,000,000 to the Skin Group. Dr. Eisenberg was paid \$85,000 in connection with this agreement as reimbursement for his expenses (\$35,000 during the period from inception (March 12, 1991) to December 31, 1991 and \$50,000 during the year ended December 31, 1992). The Other Founders initially owned all of the stock of the Skin Group (95,382 shares). On July 27, 1992, the Skin Group was merged with and into Ortec.

First private placement: In March 1991, the Skin Group issued, in a private placement, 21,744 shares for \$65,000. In June and October 1991, the Skin Group issued an aggregate 14,902 shares, to a then director of ours (the "Director") for an aggregate gross proceeds of \$250,000.

Second private placement: Commencing in November 1991, the Skin Group issued 7,948 shares under a second private placement for \$750,006. The 7,948 shares consisted of 5,302 shares issued during 1991 and 2,646 issued shares during 1992 for \$500,000 and \$250,006, respectively. Under the second private placement an additional 2,286 of our shares were issued for \$215,467. In addition, the Director was granted warrants to purchase 736 of our shares at \$94.25 per share.

ORTEC INTERNATIONAL, INC.
(A DEVELOPMENT STAGE ENTERPRISE)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Stock purchase agreement entered into with the Director: In June 1992, 5,304 of our shares were sold to the Director for a total purchase price of \$499,998. The purchase price was payable in installments and shares and warrants were issued in installments pro rata with the payment of the purchase price. During the years ended December 31, 1992 and 1993, the Director paid \$299,998 and \$200,000, respectively, and was issued 3,182 and 2,122 shares, respectively. In addition, the Director was granted warrants to purchase 7,957 shares (4,774 and 3,183 of which were granted in 1992 and 1993, respectively) at an exercise price of \$94.25 per share; such warrants were exercised on December 29, 1998.

Further, in connection with the Director's purchase of the 5,304 shares, in 1993, the Other Founders granted to the Director options to purchase from them an aggregate of 7,400 of our shares, at a price of \$50 per share. In 1993, the Director exercised such option in part, and purchased 4,900 shares from the Other Founders at the option price of \$50 per share. The remaining balance of such options expired April 15, 1994.

Third private placement: Pursuant to a third private placement that commenced on January 13, 1993, and concluded on March 31, 1993, we sold an aggregate of 10,965 shares at \$100 per share for \$1,096,500. Subsequent to such offering, in 1993, we sold an additional 2,250 shares at \$100 per share for \$225,000. In connection with such purchases, all purchasers received certain registration rights.

Stock Purchase Agreement with Home Insurance Company dated July 19, 1993: Pursuant to a Stock Purchase Agreement dated July 19, 1993, by and between us and the Home Insurance Company (Home Insurance), we sold to Home Insurance 11,112 shares of common stock for an aggregate purchase price of \$999,999, or \$90 per share. In connection with such purchase, Home Insurance received certain registration rights.

Shares issued in exchange for commission: In 1993, we issued 60 shares to an individual as compensation for commissions in connection with the sale of our shares. Such commissions are included in share issuance expenses. The stock issued was valued at \$100 per share.

In August 1993, the Director entered into a stock option agreement with Dr. Eisenberg and the Other Founders, pursuant to which he received the right to purchase an aggregate of 10,000 shares owned by such persons in various amounts and at various times, at a purchase price of \$100 per share. As of December 31, 1993, the Director had exercised options and purchased 500 shares under such agreement at \$100 per share. The remaining balance of such options has expired.

Fourth private placement: Pursuant to a fourth private placement consummated in July 1994, we sold an aggregate of 3,946 shares at between \$100 and \$125 per share for aggregate proceeds of \$397,712.

Stock Purchase Agreement with Home Insurance dated July 22, 1994: Pursuant to a Stock Purchase Agreement dated July 22, 1994, between Ortec and Home Insurance, we sold to Home Insurance 5,000 shares of common stock for an aggregate purchase price of \$500,000, or \$100 per share. In connection with such purchase, Home Insurance received certain registration rights and warrants to purchase 1,000 shares of common stock at \$120 per share, which expired on July 21, 1997.

Rent Forgiveness: During the year ended December 31, 1995, Dr. Eisenberg's father waived the rights to \$40,740 of unpaid rent which was accounted for as additional paid-in capital.

Initial Public Offering: On January 19, 1996, we completed an initial public offering of 120,000 units for aggregate proceeds of \$6,000,000. Each unit consisted of one share of our common stock, one Class A warrant to purchase one share of common stock at \$100 and one Class B warrant to purchase one share of common stock at \$150. As of December 31, 1998, 108,378 Class A warrants were exercised and the balance expired unexercised. The Class B warrants were originally set to expire in January 1999. We extended the expiration date to March 31, 2000. The Class B warrants were subject to redemption by us at \$.10 per warrant. We received gross proceeds of approximately \$1,282,000 and \$10,823,000 and net proceeds of approximately \$1,262,000 and \$10,165,000 as a result of the exercise of warrants in 1998 and 1997, respectively.

Fifth private placement: In November 1996, we completed a private placement of our securities from which we received gross proceeds of \$6,220,797 and net proceeds of approximately \$5,733,000 (after deducting approximately \$487,000 in placement fees and other expenses of such private placement). We sold 95,911 shares of common stock in such private placement at average prices of \$64.90 per share. In addition, we granted five-year warrants to placement agents to purchase

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

such number of shares equal to 10% of the number of shares of common stock sold by such placement agents, exercisable at prices equal to 120% of the prices paid for such shares. Pursuant to the purchasers' request, we registered all 95,911 shares.

Options and warrants issued for services: During 1992 and 1993, we issued warrants to purchase 666 shares at \$94.25 per share, and during 1995 we issued warrants to purchase 2,000 shares at \$100 per share to members of our Scientific Advisory Board. During 1996 and 1997, we issued warrants to purchase 24,210 shares at \$60 to \$120 per share to the Director and certain others. These warrants expired at various dates through November 2001.

On January 20, 1996, we granted "lock-up warrants" entitling shareholders to purchase an aggregate of 38,905 shares of our common stock at a price of \$10 per share. All unexercised warrants expired on January 18, 2000. At different times during 1996, seven persons exercised such warrants and purchased 3,389 shares of common stock at the \$10 per share exercise price. The issuance of such lock-up warrants was in consideration for such shareholders signing lock-up agreements agreeing not to sell or transfer shares of our common stock purchased at prices of \$90 or more per share until January 20, 1997. At different times during the third quarter of 1997, eight persons exercised such warrants and purchased an aggregate of 2,121 shares of common stock at the \$10 per share exercise price. During 1998, nine persons exercised such warrants and purchased an aggregate of 9,608 shares of common stock at the \$10 per share exercise price. During 1999, five persons exercised such warrants and purchased an aggregate of 1,410 shares of common stock at the \$10 per share exercise price. There were no underwriting discounts or commissions given or paid in connection with any of the foregoing warrant exercises.

During the third quarter of 1997, we granted to one person and its seven designees four-year warrants to purchase an aggregate of 3,750 shares of common stock, at an exercise price of \$120 per share. Such warrants were not exercisable until July 18, 1998 and were granted in consideration for consulting services rendered to us.

During the fourth quarter of 1997, we granted to one person and its six designees four-year warrants to purchase an aggregate of 3,750 shares of common stock, at an exercise price of \$120 per share. Such warrants were not exercisable until July 18, 1998 and were granted in consideration for consulting services rendered to us.

During 1998, warrants for 1,870 shares, mentioned in the two previous paragraphs, were exercised utilizing the cashless exercise option of the warrant agreement. We issued 620 shares upon this exercise.

During the third quarter of 1997, we granted to one person a one-year warrant to purchase an aggregate of 63 shares of common stock, at an exercise price of \$120 per share. Such warrants were granted in consideration for consulting services rendered to us. The warrant was exercised during 1998.

We recorded consulting expense of approximately \$65,000 as a result of these grants during the year ended December 31, 1998.

During the fourth quarter of 1997, we granted five-year warrants to our three executive officers to purchase an aggregate of 24,000 shares of common stock, at an exercise price of \$120 per share. Such warrants were granted in consideration for services rendered to us. The exercise of such warrants was contingent upon the occurrence of certain events, which were considered probable at December 31, 1997. As of December 31, 1998, five of the six events had occurred so that 18,500 of those warrants became vested. As a result, we recorded compensation expense of approximately \$80,000 in December 1997 and \$1,185,000 for the year ended December 31, 1998. The balance of the warrants became vested upon the exercise of warrants owned by a director in December 1998 in accordance with the terms of certain compensation provisions as approved by our Board of Directors.

In consideration for services rendered by him as our director in the five-year period from 1992 to 1996 for which he never received compensation, we extended by one year to December 31, 1998 the expiration date of warrants owned by a director to purchase an aggregate of 8,693 shares, exercisable at \$94.25 per share. As a result, we recorded compensation expense of approximately \$420,000, during the fourth quarter of 1997. All of these warrants were exercised on December 29, 1998.

During the fourth quarter of 1998, we granted five-year options to our three executive officers to purchase an aggregate of 52,075 shares of common stock, at exercise prices ranging from \$121.30 to \$124.40 per share. The exercise of such options was contingent upon the occurrence of certain events. All of these options became vested upon the exercise of warrants

ORTEC INTERNATIONAL, INC.
(A DEVELOPMENT STAGE ENTERPRISE)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

owned by a director in December 1998 in accordance with the terms of certain compensation provisions as approved by our Board of Directors. As a result, we recorded compensation expense of approximately \$495,000 in December 1998.

Sixth private placement: In December 1998, we completed a private placement of our securities from which we received proceeds of \$2,000,000. In addition, we granted three-year warrants to the purchaser to purchase 5,000 shares at \$120 per share. We sold 20,000 shares of common stock in such private placement. We allocated the \$2,000,000 proceeds amongst the common stock and warrants based upon the relative fair market value of the stock at the date of issuance and the estimated fair value of the warrants using the Black-Scholes option pricing model. We assigned values to the common stock and warrants issued of \$1,788,698 and \$211,302, respectively.

Seventh private placement: In March 1999, we completed a private placement of 38,916 shares of our common stock to twenty investors from which we received proceeds of \$3,405,076. In addition, each investor also received a three-year warrant to purchase 20% of the number of shares of our common stock such investors purchased in such private placement. The prices at which such warrants were exercisable was \$125 per share for one half, and \$145 per share for the other half, of the number of shares issuable upon exercise of such warrants. We allocated the \$3,405,076 proceeds amongst the common stock and warrants based upon the relative fair market value of the stock at the date of issuance and the estimated fair market value of the warrants using the Black-Scholes option pricing model. We assigned values to the common stock and warrants issued to the investors of \$3,168,785 and \$236,291, respectively. Oscar Gruss & Son, Incorporated (Gruss) acted as placement agent in such private placement. For its services as placement agent, we paid Gruss \$272,406 and granted Gruss a five-year warrant to purchase an aggregate of 3,892 shares of our common stock at an exercise price of \$105 per share. The value assigned to the Gruss warrants was \$232,000. Other share issuance costs amounted to \$106,002.

Eighth private placement: In December 1999, we completed a private placement of 163,637 shares of our common stock to two institutional funds from which we received proceeds of approximately \$9,000,000. Share issuance costs amounted to approximately \$9,500.

Ninth private placement: In March 2000, we completed a private placement of 6,667 shares of our common stock to one fund from which we received proceeds of approximately \$1,000,000. In addition, we paid a placement agent who introduced us to the fund a fee of approximately \$43,400 and granted such placement agent a five year warrant to purchase 267 shares of our common stock at an exercise price of \$150 per share. The value assigned to the warrant was \$23,000, which was reflected as share issuance costs. Other share issuance costs amounted to \$3,200.

Tenth private placement: In September 2000, we completed a private placement of 124,757 shares of our common stock to ten investors from which we received approximately \$8,421,000. In addition, we paid the placement agent who introduced us to the investors a fee of approximately \$525,400. Other share issuance costs amounted to approximately \$46,500.

Options issued for services: In April 2001, we issued options to purchase 6,000 shares of our common stock, at \$69.50 per share, to certain professionals. The estimated fair value of \$188,080 for such options was charged to general and administrative expenses.

During 2002, we completed a private placement with several investors, in which we raised cash proceeds of \$8,200,000, issued convertible preferred shares, issued warrants to purchase common shares and granted common stock as dividends. (See Note 12).

During July 2003, we granted a warrant to purchase 150,000 shares at an exercise price of \$2.00 per share to a vendor in consideration for twelve months of consulting services. In accordance with the agreement, 50% of the shares, or 75,000 shares, vested immediately, with the balance vesting upon the six-month anniversary in January 2004. As a result, we recorded expense of \$87,000 in 2003 and \$94,393 during 2004 representing the value of the additional 75,000 shares which had vested.

Restricted Share Grant: During 2003, an allocation of 1,800,000 restricted shares of common stock were granted to officers and certain employees. The issuance of these shares was contingent on our achieving certain milestones.

On January 5, 2005, we issued 1,000,000 and 340,000 of these shares to our chief executive officer and chairman, respectively, for having achieved a milestone of raising in excess of \$15,000,000 over a specified period. On June 27, 2005,

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

we allocated the remaining 460,000 shares of our common stock to certain executive officers and other employees. We issued an aggregate of 295,000 shares to our Chief Operating and Chief Financial Officers. Grants of the remaining 165,000 shares allocated to three employees were conditioned on meeting certain performance criteria. One of those employees met such performance criteria at December 31, 2005 and 10,000 shares were issued. Until such time as the three employees meet the balance of their performance criteria, the fair value of the 155,000 shares will be adjusted at each reporting period. The related charges will be reflected as additional paid in capital and deferred compensation in the statement of shareholders' deficit. The shares will vest in five equal monthly installments commencing January 1, 2007. However, the portion of the shares granted to such officer or employee which are not vested will be forfeited if the officer or employee is then no longer employed by us at any time after January 1, 2007. The shares may only be sold in five monthly installments commencing January 1, 2007. We recorded a charge to deferred compensation of \$751,584 based on the fair value of these restricted shares. The deferred compensation for the 1,645,000 issued shares is being amortized over the 29-month vesting period. Included in general and administrative expense is a charge of \$289,139 for the year ended December 31, 2005 reflecting the amortization of this deferred compensation amount. These shares have certain registration rights. In lieu of a direct cash payment, these individuals may transfer a portion of their shares back to us to satisfy their minimum future personal tax withholding liability arising from the receipt of these shares for which we will pay their tax obligation.

Promissory Note Transactions: In connection with the issuance of \$9,776,626 of promissory notes to investors placed in 2003 and 2004, we paid our placement agent a fee equivalent to 50 shares for every \$1,000 of the promissory notes and recorded this as deferred debt issuance cost which was then amortized over the life of the note to interest expense. 488,831 shares were issued in 2004 consisting of 157,000 shares valued at \$287,000 (in 2003) relating to notes placed in 2003 and 331,831 shares valued at \$746,202 relating to notes placed in 2004.

On October 27, 2004 holders of \$9,206,000 of investor promissory notes agreed to extend the maturity date of their notes from November 5, 2004 to December 31, 2004. In consideration of this extension we increased the interest rate for the fourth quarter of the calendar year to 12% and issued 45,000 common shares for each \$1,000,000 of principal amount held, or 414,270 common shares, which we issued in 2005. The modification was not considered significant and thus these shares were valued at \$2.00 per share, or \$828,540 in the aggregate, and was charged to interest expense in the fourth quarter. These shares were issued in 2005 upon our confirmation of each noteholders' accredited investor status. In connection therewith, we issued 277,020 shares of common shares and 34.31 shares of our Series D preferred stock (equivalent to 137,250 common shares).

As provided in the promissory notes, if we received \$5,000,000 of gross proceeds from a qualified financing, we may elect to prepay the notes and any accrued and unpaid interest in cash or in our stock. See January 5, 2005 private placement discussion below.

Special Warrant Offer: On November 16, 2004, we made a Special Warrant Offer (SWO) to all holders of our Series B-1, B-2 and C warrants. Such warrants were originally issued in connection with our Series B and Series C preferred stock financings in November and December 2002 and in February, May and July 2003 (See Note 13). At the time of the SWO there were outstanding and eligible for the SWO: 667,989 and 25,000 Series B-1 warrants exercisable to purchase our common stock at \$4.00 and \$15.00 per common share, respectively; 544,138 and 25,000 Series B-2 warrants exercisable to purchase our common stock at \$5.00 and \$20.00 per common share, respectively, and 1,707,000 Series C warrants to purchase our common stock at \$3.60 per common share. Under the terms of the SWO, the holders were entitled to purchase 1/3 of such shares they could otherwise purchase at a reduced exercise price of \$1.67 per common share. Concurrently with such exercise they would receive 2/9 of such shares they could otherwise purchase at the reduced exercise price of \$0.01 per common share, and they would surrender the right to purchase their remaining 4/9 of such shares they could otherwise purchase. Each warrant holder participating in the SWO received a new warrant to purchase 30% of the common shares acquired by such purchaser in the SWO.

The SWO was concluded December 3, 2004. Holders of 491,791 of our Series B-1 warrants, 431,341 of our Series B-2 warrants, and 1,605,000 of our Series C warrants participated in the SWO.

Participation in the offering resulted in aggregate gross proceeds of \$1,438,019 consisting of cash proceeds of \$1,338,019 and \$100,000 relating to the settlement of an existing promissory note obligation. There were no fees paid to our placement agent in connection with the SWO. We issued 496,981 shares of our common stock and 233.8274 shares of Series D convertible preferred stock, which are equivalent to 935,310 shares of common stock. We also issued five-year Series E

ORTEC INTERNATIONAL, INC.
(A DEVELOPMENT STAGE ENTERPRISE)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

warrants to the investors to purchase an additional 429,689 shares of our common stock for \$1.80 per share.

As a result of the SWO, the warrant holders who participated in the offering were considered to have received a deemed dividend aggregating \$1,120,500 based upon a Black Scholes calculation considering the valuation of the warrants prior to the November 16, 2004 offering and subsequent to the offering. We recorded an aggregate deemed dividend of \$1,123,000 inclusive of Paul Royalty Fund's SWO described in Note 9.

January 2005 private placement: On January 5, 2005 we entered into a number of agreements with institutional and accredited investors (collectively, the "purchasers") that provided us with:

- Gross aggregate cash proceeds of \$5,403,302 from the sale of our common stock (the "private placement") to former holders of our Series C preferred shares and other purchasers at \$0.833 per share (the "purchase price") with each receiving a five year warrant to purchase one share of common stock at \$1.80 per share for every two shares purchased;
- The exchange of all our outstanding Series C preferred shares at January 5, 2005, or approximately 913 Series C preferred shares, with a liquidation preference of \$5,476,256 plus accrued and unpaid dividends, an aggregate value of \$6,357,104, for shares of our common stock at the \$0.833 per share purchase price and five-year warrants to purchase our common stock at \$1.80 per share. Upon the exchange, the holders of the Series C preferred shares received a warrant to purchase one share of common stock for each two shares of our common stock they received in the exchange. This exchange was offered to Series C preferred shareholders if they participated in the private placement sale of our common stock for an amount equal to 30% of the liquidation preference amounts of their Series C preferred shares exchanged for our common stock. The Series C holders provided gross cash proceeds of \$1,642,877 (30% of \$5,476,256) of the \$5,403,302 aggregate gross proceeds received by us in the private placement. We recorded a deemed dividend of \$2,125,974 related to the value of warrants issued in the exchange of the Series C preferred shares for common shares.
- As a result of our receipt of over \$5,000,000 in the private placement we elected to repay \$9,626,626 (principal balance outstanding at January 5, 2005) of our outstanding promissory notes, accrued interest of \$674,587 and an added 20% premium, in all \$12,361,456, by issuing to each noteholder so many shares of common stock equal to the principal, accrued interest and premium of each divided by the \$0.833 purchase price. Each noteholder also received a five-year warrant to purchase one share of our common stock at \$1.80 per share for each common share received, or approximately 15,000,000 Series E warrants. We recorded a loss on settlement of \$10,328,199 in connection with this transaction representing the beneficial conversion feature and discount on the notes from issuance of the warrants and the final conversion terms. This amount was expensed immediately upon conversion of the notes.
- Purchasers, Series C Holders and holders of the Notes whose participation in these transactions would result in ownership of common stock in excess of 9.99% of our issued and outstanding shares of common stock could elect to receive instead of our common stock, shares of our Series D convertible preferred stock convertible into the same number of shares of our common stock.

We issued an aggregate 17,720,767 shares of common stock, 2,806.37 shares of Series D preferred stock (convertible into 11,225,466 shares of common stock), and five-year Series E warrants to purchase 21,889,989 shares of our common stock at an exercise price of \$1.80 per share, as a result of these transactions.

We granted each of the purchasers in the \$5,403,302 private placement the right to purchase, within 45 days after the closing date, additional shares of our common stock and our Series E warrants on the same terms as in the private placement in an amount not to exceed 25% of their original cash investment in the private placement. Four investors exercised this right and we received gross proceeds of \$127,719. We issued 153,263 shares and five year warrants to purchase 76,632 shares of our common stock at an exercise price of \$1.80 per share for such additional investments by these four investors.

The Series E Warrants, with certain exceptions, provide that if we sell shares of our common stock at prices below the exercise prices of those warrants, or issue other securities convertible into, or which entitle the holder to purchase, shares of

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

our common stock, which could result in the sale of our common stock at a price which in effect (taking into consideration the price paid for the convertible security or the warrant or the option) is less than the exercise price of the Series E Warrants, then the exercise price of the Series E Warrants will be reduced by a portion of the difference between the exercise price and the lower price at which the common stock was, or effectively could be, acquired. That percentage by which the exercise price of the Series E Warrants could be reduced depends not only on the lower price at which our common stock was, or could be, acquired, but also by the ratio that the number of shares of our common stock that were, or could be, so acquired bears to the total number of shares of our common stock that would be outstanding after such sale of our common stock, or the conversion of securities convertible into, or the exercise of such warrants or options to purchase, our common stock.

After January 5, 2007, subject to a registration statement then being effective for the common stock underlying the warrants, the warrants may be redeemed by us, through expiration, if our common stock closes above \$3.60 for ten consecutive trading days. The warrants contain cashless exercise as well as other customary anti-dilution provisions.

In connection with these transactions, we paid Burnham Hill Partners, a division of Pali Capital ("BHP"), our placement agent, commissions consisting of cash equaling 10% of the \$5,403,302 of gross cash proceeds we received from the private placement. The placement agent and his assigns received warrants to purchase 2,728,376 shares of our common stock exercisable at \$0.95 per share. We paid \$86,872 in legal and accounting expenses in connection with the private placement. At any time in the next three years, we will pay the placement agent cash equal to 6% of the gross proceeds received by us from the exercise of the warrants issued to the investors who purchased shares of common stock for cash in the private placement. We also entered into an agreement under which the placement agent provided financial advisory services to us through September 30, 2005, for a fee of \$250,000. The fee was amortized over the period of service. The agreement provided that payment of such fee would be deferred until our cash balance exceeds \$10,000,000. Pursuant to a new advisory agreement dated September 23, 2005, we agreed that the placement agent may apply all or a portion of the \$250,000 Advisory Fee as purchase price for the common stock and common stock purchase warrants sold in the financing which we closed October 12, 2005.

Series B conversion: In accordance with an agreement dated May 23, 2003 amongst the holders of Series B preferred stock which provided for conversion of our outstanding Series B preferred stock should all of the holders of Series C preferred stock convert their preferred shares to common stock (which occurred at the January 5, 2005 closing as described above), Paul Royalty Fund, the sole remaining holder of Series B preferred stock converted their 50 shares of Series B preferred stock into 220,647 shares of common stock, which included common shares for \$51,616 in accrued dividends.

February 2005 private placement On February 9, 2005, we completed a private placement with one investor from which we received aggregate gross proceeds of \$100,000. We issued to the investor 120,000 shares of our common stock and a five-year warrant to purchase 60,000 shares of our common stock at \$1.80 per share. We paid our placement agent 10% of the gross proceeds and a five-year warrant to purchase 18,000 shares of our common stock exercisable at \$0.95 per share. We incurred legal expenses of \$3,727 for this transaction.

We had undertaken to register all shares of our common stock in our January 5 and February 9, 2005 private offerings as well as all shares of our common stock issuable upon exercise of all the warrants and conversion of Series D preferred stock issued in the January 5, 2005 offering, within 10 days after filing of our Annual Report on Form 10-KSB with the Securities and Exchange Commission, which Form 10-KSB we filed on March 31, 2005. In April 2005, in consideration for the waiving of penalties we would have to pay for failure to file our registration statement at a date no later than April 13, 2005, we entered into agreements with our Series E Warrant holders who purchased our common stock and received registration rights in our January 5 and February 9, 2005 private offerings, to modify the price of their Series E Warrants from \$1.80 to \$1.50. Utilizing a Black Scholes valuation model we recorded a deemed dividend to these warrant holders of \$67,217.

2005 Convertible Promissory Note Financing: Beginning May 27, 2005 and thereafter, we received gross proceeds of \$3,186,000 through the issuance of 8% promissory notes due December 31, 2005. The outstanding principal together with all unpaid and accrued interest would automatically convert into equity securities issued by us in an equity financing or a combination of equity financings with gross proceeds of at least \$5,000,000, such conversion to be at the same price per equity security as the equity securities sold in the equity financing; provided, however, that for purposes of determining the number of equity securities including warrants to be received upon such conversion, the dollar amount due the noteholder will first be multiplied by a factor of 1.2 times. In consideration of such financing the exercise price of the noteholders'

ORTEC INTERNATIONAL, INC.
(A DEVELOPMENT STAGE ENTERPRISE)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Series E warrants to purchase 11,983,445 shares of common stock received in our January 5, 2005 private placement where we sold stock at \$.833 per share, were reduced from an exercise price of \$1.80 and \$1.50 per share to an exercise price of \$.001 per share. Utilizing a Black Scholes valuation model we recorded a deemed dividend to these warrant holders of \$2,212,436. Additionally, an investor holding in excess of 9.99% of our shares on a fully diluted basis who purchased \$150,000 of those promissory notes, entered into a funding commitment for an additional \$1,208,000. The exercise of such investor's repriced warrants to purchase 3,618,797 shares of our common stock is limited to an amount determined by multiplying the 3,618,797 warrants by the percentage of the \$1,358,000 commitment actually funded. Such investor must provide us with such additional \$1,208,000 by the later of the filing of our pre-market approval application for our confirmatory venous leg ulcer trial, or March 31, 2006. We received \$150,000 towards this amount on September 14, 2005 in the form of a loan for which we issued an 8% promissory note (to be automatically converted into our equity securities the same as our other promissory notes, described above). That left a balance to be paid to us under that commitment of \$1,058,000. We paid a cash fee of 5% of the gross loan proceeds to our financial advisor in connection with all such loans. See Note 18 regarding a further advance against the outstanding loan commitment.

On September 29, 2005 we received an additional \$150,000 in the form of an 8% promissory note due December 31, 2005 with similar terms to the \$3,186,000 of promissory notes issued in the prior quarter.

On October 12, 2005, the terms of all of the \$3,486,000 of outstanding promissory notes at September 30, 2005 were amended to reduce the amount of gross proceeds we had to receive in equity financings to trigger the conversion of the notes to our equity securities, from the original \$5,000,000 to \$2,514,000. In consideration of this amendment the holders received 20,000 seven-year Series F warrants to purchase our common stock at \$0.50 per common share for each \$100,000 of outstanding principal amount of the note that is being converted into our equity securities, or 697,200 Series F warrants. As a result of our receipt of gross proceeds of approximately \$2,650,000 from the sale of our equity securities on October 12, 2005, all of the promissory notes we issued after May 26, 2005, including accrued interest of \$98,463 and an added 20% premium, in all \$4,301,355 were converted into an aggregate of 17,205,421 shares of our common stock. We actually issued 6,346,925 shares of our common stock and 2,714,624 Series D Preferred (equivalent to 10,858,496 shares of common stock), and Series F warrants to purchase an additional aggregate 9,299,910 shares of common stock at \$0.50 per share. We recorded a loss on settlement of \$2,753,254 in connection with this transaction representing the beneficial conversion feature and discount on the notes from issuance of the warrants and the final conversion terms. This amount was expensed immediately upon conversion of the notes.

Cambrex Suite Deal: On July 12, 2005, we entered into an agreement with our manufacturing and marketing partner, Cambrex Bio Science Walkersville, Inc. whereby for the six-month period May 1 to October 31, 2005 the \$128,750 monthly charges we incur for rental of a production suite used to produce ORCEL at their Maryland facility will be accrued by them for later conversion into shares of our common stock and warrants. The aggregate accrued charge during the six-month period of \$772,500 will be converted at \$0.75 per common share, or 1,030,000 shares of common stock. Concurrently with the conversion we will also issue three year warrants to purchase an amount representing 1.5 times the number of shares of our common stock, or 1,545,000 shares, at \$1.80 per share. Each of these securities will carry certain registration rights. At December 31, 2005, we have accrued a charge for the six month period from May 1 to October 31, 2005 based on the fair value of the 1,030,000 shares and warrants to purchase 1,545,000 shares of our common stock at \$1.80 per share. Accordingly, we have recorded a liability of \$235,500 to reflect the fair value of our common stock and warrants to be issued as payment for the production suite. We entered into a similar arrangement in 2006. See Note 18, Cambrex Suite Deal II.

Service Agreement: On July 18, 2005, we entered into a three-month service agreement with a financial communications group whereby we agreed to grant it a warrant to purchase 50,000 shares, exercisable as follows: (i.) 25,000 shares exercisable at \$0.50 per share, which vested immediately, and (ii.) 25,000 shares exercisable at \$1.00 per share, which vested upon the Company and the financial communications group extending the term of the service agreement. Utilizing a Black-Scholes valuation model we recorded a general and administrative charge of \$4,903 for these warrants.

On December 1, 2005, in partial consideration for services rendered by it to us we granted one company three-year warrants to (i) purchase 25,000 shares of our common stock at an exercise price of \$0.50 per share, which will vest on March 31, 2006 immediately, and (ii) to purchase an additional 25,000 shares of our common stock at an exercise price of \$1.00 per share, which vest only if we and the service provider extend the original three-month term of the service agreement beyond March 31, 2006. Utilizing a Black-Scholes valuation model we recorded a general and administrative charge of \$2,286 for the initial warrant to purchase 25,000 shares at \$0.50 per share.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

October 2005 Private Placement: On October 12th and 31st, 2005, in a private placement in which we agreed to issue common stock at a purchase price of \$0.25 per share we received aggregate gross proceeds of \$3,647,691 (approximately \$2,650,000 of which was received on October 12, 2005) for which we issued 14,590,764 shares and each purchaser received our Series F common stock purchase warrants to purchase 50% of the number of common shares purchased, or an aggregate of 7,295,382 shares. The Series F warrants are exercisable at \$0.50 per share. Investors holding an aggregate 5,881,079 Series E warrants who purchased our common stock and Series F warrants in this most recent private placement in an amount equal to at least 40% of their past cash investments in our January 5, 2005 equity private placement (which was completed at \$0.833 cents per share and in which they purchased our common stock and our Series E warrants), or who converted our promissory notes on that January 5, 2005 date to shares of our common stock and Series E warrants, had the exercise price of their Series E warrants held by them reduced to \$.001 from \$1.80 and \$1.50 per share. The modification of the warrant value was recorded as a deemed dividend of \$1,053,088 based on a Black Scholes valuation.

Purchasers whose participation in our most recent private placement whose holdings would result in ownership in excess of 9.99% of our outstanding common stock were given the option to receive our Series D preferred shares which will be convertible to the same number of shares of our common stock they would otherwise acquire in this current private placement.

The Series F warrants contain certain anti-dilution provisions. We may redeem the Series F warrants at any time after twelve months after their issuance should our common stock trade above \$1.00 for ten consecutive trading days.

We are required to file a registration statement registering the shares of the common stock and the shares of our common stock issuable upon exercise of our Series F warrants, which we sold in our most recent private placement. That registration statement was required to be filed no later than January 6, 2006. We are required to use our best efforts to have the registration statement declared effective within 60 business days thereafter. Such registration rights agreement provided, before it was modified, that if the registration statement was not filed by January 6, 2006, or was not declared effective within 90 business days of its filing we must pay the investors cash liquidated damages equal to 1.5% of the amount they invested in the current private placement for the first 30 days of our default, and 1% of the amount invested for each 30 days thereafter. See Note 19 regarding modification of the registration rights agreement.

BHP received a cash fee equal to 10% of the gross proceeds (including cash received for our promissory notes issued since May 2005, approximately half of which we paid to BHP upon placement of the notes) received by us in this most recent private placement. BHP received warrants to purchase 3,179,619 shares of our common stock at an exercise price of \$0.30 per common share. BHP has the option to take \$174,300 of their fee to purchase our common stock and our Series F warrants at the same price as paid by the investors in this most recent private placement for those securities. Additionally, as a result of such private placements and sale of our promissory notes, pursuant to our agreement with BHP, placement agent warrants for the purchase of 2,746,376 shares of our common stock at an exercise price of \$0.95 per share, which we issued to BHP and its designees in connection with the private placement of our common stock and our Series E warrants which closed on January 5, 2005, had their exercise price reduced to \$0.35 per share. The modification of the warrant value was recorded as a deemed dividend of \$143,942 based on a Black Scholes valuation. We paid \$109,306 in legal and accounting expenses in connection with the private placement. For a period of 36 months ending in October 2008 we shall pay BHP a cash fee of 6% of the proceeds we receive from the exercise of any of our warrants issued to investors who paid cash for our securities.

For a period of nine months ending July 31, 2006, BHP had the right to act as our exclusive placement agent in connection with our subsequent financings. During that period, BHP would have been entitled to an industry standard fee for completion of a strategic transaction by us. BHP has waived its right to act as placement agent with respect to a proposed private placement financing we have to complete and has waived its fee for a proposed strategic transaction we are negotiating. Pursuant to rights granted to it BHP has applied the \$250,000 advisory fee it earned under the advisory agreement between us and BHP dated January 4, 2005 and \$174,300 of commissions owed by us to BHP, to purchase our common stock and Series F warrants at the same price as paid by the investors in this most recent private placement for these securities.

Purchasers in our most recent private placement, both those who purchased on October 12, 2005 and on October 31, 2005, have the right for a period which ends on the earlier of six months after their purchase of our common stock and our Series F warrants, or upon our announcement of a transaction in which we will issue at least 20,000,000 shares of our common stock (a "Material Transaction"), to participate in any equity financing by us in connection with or relating to such Material

ORTEC INTERNATIONAL, INC.
(A DEVELOPMENT STAGE ENTERPRISE)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Transaction, so that each purchaser can maintain its percentage ownership of our common stock as of the date immediately prior to the date of such equity financing.

The exercise prices of our Series F warrants issued to the purchasers in our most recent private placement on October 12, 2005 and on October 31, 2005, and to the note holders, will be adjusted if during the earlier of (a) the six-month period after the date of issuance of the Series F warrants, or (b) when we announce a Material Transaction,

- (i) we sell our equity securities in a financing at a price equal to or greater than \$0.25 per share, the exercise price of our Series F warrants held by such persons will be reduced (or increased but not beyond the current \$0.50 per share exercise price of our Series F warrants) to the exercise price of the warrants issued in such equity financing, or
- (ii) we sell our equity securities in a financing for less than \$0.25 per share (notwithstanding that such equity financing is consummated following the announcement of the Material Transaction), the exercise price of our Series F warrants held by such persons will be reduced to the price per share for which we sell our equity securities in such financing.

In a press release dated December 15, 2005, we announced our letter of intent to acquire Hapto Biotech (see Note 14). We considered this a Material Transaction. The sale of our common stock and our Series F warrants in our most recent private placement is exempt from the registration requirements of the Securities Act of 1933, as amended (the "Act") pursuant to the provisions of Regulation D promulgated under the Act, since all the purchasers were accredited investors, as that term is defined in Rule 501 in Regulation D.

In October and November 2005, we issued seven-year options to purchase an aggregate of 3,179,619 shares of our common stock at \$0.25 per common share, the fair value of our common stock on the date of the grant, to each of our chairman and our chief executive officer. These options represent the bonus due them under their compensation arrangement with us for the completion of the October 2005 private placement. See Note 12.

The following table summarizes warrant activity during the period from March 12, 1991 (inception) through December 31, 2005 (excluding the Class A and B warrants which were issued during the IPO):

ORTEC INTERNATIONAL, INC.
(A DEVELOPMENT STAGE ENTERPRISE)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

	Price Range (\$)		Warrants
March 12, 1991 (inception)			
Granted		94.25	736
Balance, December 31, 1991		94.25	736
Granted		94.25	5,508
Balance, December 31, 1992		94.25	6,244
Granted	94.25	- 120.00	4,823
Balance, December 31, 1993	94.25	- 120.00	11,067
Granted		120.00	1,000
Balance, December 31, 1994	94.25	- 120.00	12,067
Granted		100.00	400
Expired		94.25	(268)
Balance, December 31, 1995	94.25	- 120.00	12,199
Granted	10.00	- 100.00	51,161
Exercised		100.00	(3,389)
Expired		120.00	(245)
Balance, December 31, 1996	10.00	- 120.00	59,726
Granted	120.00	- 142.50	33,063
Expired		120.00	(1,000)
Balance, December 31, 1997	10.00	- 142.50	91,789
Granted	120.00	- 140.00	7,500
Exercised	10.00	- 120.00	(20,585)
Expired		120.00	(10,843)
Balance, December 31, 1998	10.00	- 142.50	67,861
Granted	125.00	- 145.00	11,674
Exercised		10.00	(1,410)
Expired	60.00	- 94.25	(1,716)
Balance, December 31, 1999	10.00	- 142.50	76,409
Granted		150.00	267
Exercised		120.00	(200)
Expired	10.00	- 100.00	(15,499)
Balance, December 31, 2000	77.00	- 150.00	60,977
Expired	77.00	- 120.00	(21,436)
Balance, December 31, 2001	77.00	- 150.00	39,541
Granted	.01	- 62.48	2,221,015
Exercised		.01	(973,997)
Expired	.01	- 145.00	(169,348)
Balance, December 31, 2002	.01	- 150.00	1,117,211
Granted	.01	- 15.00	2,369,212
Exercised	.01	- 4.00	(398,750)
Expired		140.00	(2,500)
Balance, December 31, 2003	.01	- 120.00	3,085,173
Granted	.01	- 15.00	518,741
Exercised	.01	- 20.00	(1,464,759)
Surrendered	3.60	- 20.00	(1,145,836)
Expired		140.00	(4,716)
Balance, December 31, 2004	2.00	- 120.00	988,603
Granted	0.001	- 1.80	44,622,911
Exercised		0.001	(3,658,513)
Expired	45.00	- 120.00	(3,866)
Balance, December 31, 2005			41,949,135

ORTEC INTERNATIONAL, INC.
(A DEVELOPMENT STAGE ENTERPRISE)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

The following table summarizes warrant data as of December 31, 2005:

Range of exercise prices	Number outstanding	Weighted Average Remaining contractual Life (years)	Weighted Average Exercise Price	Number exercisable
\$.001 to \$1.00	36,862,298	5.50	\$.28	36,862,298
\$1.50 to \$1.80	4,531,789	4.01	\$1.75	4,531,789
\$2.00 to \$5.00	555,048	2.63	\$3.57	555,048
	<u>41,949,135</u>			<u>41,949,135</u>

11 - SERIES A, B, C, & D PREFERRED STOCK, 12% CONVERTIBLE DEBENTURES

Series A Convertible Preferred Stock: On June 25, 2002, our board of directors unanimously adopted an amendment to our certificate of incorporation designating 2,000 shares out of the 1,000,000 shares of preferred stock that we are authorized to issue, as Series A convertible preferred stock, and designating the relative rights and preferences of the Series A convertible preferred stock. The stated value, which is also the liquidation preference of the Series A convertible preferred stock, was \$10,000 per share. We were required to pay dividends on the Series A preferred shares, at the rate of 6% per annum of the \$10,000 liquidation preference per share, through June 30, 2003; at the rate of 9% per annum thereafter until June 30, 2004; and thereafter at the rate of 12% per annum. At our option such dividends could be paid in our common stock at the "conversion price" for the conversion of such dividends if such shares of common stock had been registered under the Securities Act of 1933 for sale in the public securities markets. The conversion price was fixed initially at \$15.00 per share of our common stock. There are no shares of Series A convertible preferred stock outstanding. In November 2004, the designation establishing the rights and preferences of the Series A convertible preferred stock was eliminated from our certificate of incorporation so that we are no longer authorized to issue any more Series A convertible preferred stock.

Series B Convertible Preferred Stock: On November 7, 2002, our board of directors adopted an amendment to our certificate of incorporation designating 1,200 shares out of the 1,000,000 shares of preferred stock that we are authorized to issue, as Series B convertible preferred stock at a stated value of \$10,000 per share. Dividends on the Series B preferred shares were payable at the rate of 12% per annum, in cash or shares of common stock, at our option, except that in the first year, dividends were payable, in advance, in shares of common stock.

The Series B preferred stock was convertible into common shares at any time at the option of the investor, based on a fixed conversion rate of not less than \$3.00, or commencing after February 1, 2003, based on an alternative conversion rate equal to 90% of the average of the five lowest volume weighted average prices for our common stock for the twenty trading days immediately prior to conversion, subject to a floor price of \$2.50.

Series C Convertible Preferred Stock: On May 23, 2003, our board of directors adopted an amendment to our certificate of incorporation designating 2,000 shares out of the 1,000,000 shares of preferred stock that we are authorized to issue, as Series C convertible preferred stock at a stated value of \$6,000 per share. Dividends on the Series C preferred shares are payable at the rate of 10% per annum, in cash or shares of common stock, at our option.

The Series C preferred stock was convertible into common shares at any time at the option of the investor, based on a fixed conversion rate of \$2.00 per share.

Series B & C – Elimination of Designation: On June 16, 2005, the designations establishing the rights and preferences of our Series B and C convertible preferred stock, of which no shares were any longer outstanding, were eliminated from our certificate of incorporation so that we are no longer authorized to issue any more Series B or C convertible preferred stock.

Series D Convertible Preferred Stock: On August 19, 2003, our board of directors adopted an amendment to our certificate of incorporation designating 2,000 shares out of the 1,000,000 shares of preferred stock that we are authorized to issue, as Series D convertible preferred stock at a stated value of \$10,000 per share. In the event we declare a cash dividend on our common stock we will be required to pay a dividend on each share of our Series D preferred stock in an amount

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

equal to the cash dividend paid on one share of our common stock multiplied by the number of shares of our common stock into which such one share of our Series D preferred stock can be converted.

Each holder of Series D preferred stock may, at such holder's option, subject to certain limitations, elect to convert all or any portion of the shares of Series D preferred stock held by such holder into a number of fully paid and nonassessable shares of our common stock equal to the quotient of (i) the Series D liquidation preference (\$10,000 per Series D preferred share) divided by (ii) the Series D conversion price of \$2.50 per share. The conversion price is subject to customary adjustments to the Series D conversion price in the event of stock splits, stock combinations, stock dividends, distributions and reclassifications and other corporate events.

Issuance of 12% Convertible Debentures: In March 2002, we engaged an investment-banking firm to act as our advisor and to assist in raising capital for us in the form of either debt or equity financing.

On May 13, 2002, we issued \$2,333,000 of 12% convertible debentures, which were convertible into common shares at the lesser of \$3.36 or the price per share of the equity securities to be issued in a subsequent financing. These debentures, payable April 10, 2003, bore interest at the rate of 12% per annum, up to October 10, 2002 and 18% thereafter. We also issued 291,000 stock purchase warrants as part of this May 13, 2002 financing, exercisable at \$4.50 per share for up to five years from the date of grant. The warrants had price protection features whereby the price of the warrants can be reduced to the prices at which common stock or common stock equivalents are thereafter sold by us.

On June 28, 2002, \$600,000 of these debentures sold on May 13, 2002 were converted into Series A preferred stock at 110% of face value. Additionally, on June 28, 2002, we issued an additional \$250,000 of 12% convertible debentures and \$1,200,000 in Series A convertible preferred stock. The total face value of the preferred stock issued was \$1,870,000 which consisted of the \$1,200,000 of cash proceeds received, the \$600,000 face value of converted debentures and the \$70,000 of additional conversion face value. Additionally, the Series A preferred stock was convertible into common shares at a rate of \$1.50 per share. The Series A preferred stock had provisions whereby redemption was out of our control; therefore, the preferred stock was classified as temporary equity.

On June 28, 2002, we also issued 654,624 common stock purchase warrants, at an exercise price of \$1.875 per common share for a five-year period. Of the 654,624, an aggregate of 31,250 warrants were issued with the convertible debentures, with the remainder issued with the Series A preferred stock. The warrants also had similar price protection features, whereby the price of the warrants can be reduced to the prices at which common stock or common stock equivalents were thereafter sold by us.

During the third quarter 2002, we issued \$1,425,000 in convertible debentures, with terms comparable to those issued in the second quarter. Additionally, 178,127 warrants were issued with similar terms to warrants issued on May 13, 2002. In October and November 2002, prior to our Series B preferred stock financing, we issued an additional \$1,900,000 in convertible debentures and 237,503 warrants, with terms comparable to those issued earlier in 2002.

We deferred the payment of interest due on June 30 and September 30, 2002, pending the completion of our Series B preferred stock financing. These debentures along with the accrued interest were convertible into equity securities if we completed the sale of at least \$5,000,000 in equity securities by July 12, 2002, which date was extended through November 13, 2002. On November 13, 2002, these debentures and accrued interest were converted into Series B preferred stock with the closing of the Series B preferred stock financing. These were converted at the rate of 110% of the debentures plus accrued interest into \$10,000 par value Series B convertible preferred shares.

The relative estimated fair value of the warrants issued in connection with the debentures of \$440,523 was recorded as debt discount, as well as the estimated fair value of the beneficial conversion features of \$1,042,663. Both of these values were being amortized over the remaining life of the convertible debentures, or through April 10, 2003. Upon conversion, the remaining unamortized beneficial conversion features were charged to interest expense.

The relative estimated fair value of the warrants issued in connection with the Series A preferred stock of \$797,919 was recorded as a discount to the preferred stock and was reflected as interest expense, on the date of issuance. Additionally, the estimated fair value of the beneficial conversion feature of \$859,256 has been recorded as an additional discount and reflected as interest expense. The Series A preferred stock had no redemption date, and therefore the charge to interest expense was reflected immediately as the conversion privilege was exercisable immediately.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

First Sale of Series B Convertible Preferred Stock: In November and December 2002, we issued 938,2742 shares of Series B convertible preferred stock to several investors in a private placement for an aggregate of \$8,178,000, which included \$1,070,000 of new Series B preferred stock and the conversion of the aforementioned convertible debentures and convertible Series A preferred stock. We recorded a loss on extinguishment of debentures and preferred shares of \$1,004,027, principally due to the additional buying power granted to the investors resulting from the difference between the present value of the original debt and the revised present value. The convertible debentures and convertible Series A preferred stock were converted at 110% of face value plus accrued interest. In addition, these investors were granted Series A warrants to purchase 938,275 shares of our common stock at an exercise price of \$.01. These Series A warrants vested immediately and were exercised immediately, upon grant. The investors were also granted Series B-1 and B-2 warrants, which could be used to purchase 542,989 and 469,138 shares of common stock at an exercise price of \$15.00 and \$20.00 per share, respectively. These B-1 warrants were exercisable beginning August 13, 2003 and expire seven years from the date of grant and the B-2 warrants were exercisable beginning November 13, 2003 and expire seven years from date of grant. We assigned values to the Series B preferred stock of \$9,382,742 and the Series A, B-1 and B-2 warrants issued to the investors of \$2,245,206, \$694,447 and \$539,390, or \$3,479,043 in the aggregate, based upon the relative fair market value of the stock at the date of issuance and the estimated fair market value of the warrants, using the Black-Scholes option pricing model.

The warrants issued with the second quarter and third quarter 2003 financings were exchanged for B-1 warrants, issued in the fourth quarter of 2003.

The first year's dividends on the Series B preferred stock were paid in advance in common shares at the rate of 12% upon issue of the preferred shares and were to be paid semiannually in subsequent years, in either cash or common shares, at our election, until the preferred stock is converted to common shares. For the first year dividends totaling \$1,125,559, paid in common stock, the investors were issued 375,315 shares of common stock, of which 293,489 shares were issued in November 2002 and 81,826 shares in January 2003.

In addition, certain of the investors were given options to purchase, for one year and for amounts ranging from 100% to 200% of their investments, additional shares of the Series B convertible preferred stock at the price paid for such stock by investors on November 13, 2002.

H.C. Wainwright & Company, Inc. (Wainwright) acted as placement agent in this private placement. For its services as placement agent, we paid Wainwright \$601,490. Legal and other professional fees totaled \$155,997. All but \$136,046 of the \$755,487 aggregate costs was amortized to interest expense when the \$5,908,000 convertible debentures and \$1,200,000 of Series A preferred stock were converted to Series B preferred stock. In connection with the Series B conversion, we granted Wainwright and its agents warrants to purchase 800,000 and 500,000 shares of common stock, at an exercise price of \$.01 and \$15.00, respectively, exercisable immediately upon issue and August 13, 2003, respectively. These warrants expired on January 31, 2003 and will expire seven years from issue, respectively. In December 2002, we issued 35,273 shares of common stock upon exercise of the \$.01 warrants granted to Wainwright. The fair market value assigned to the Wainwright warrants was \$280,000 and \$24,615, or \$304,615 in the aggregate, for the \$.01 warrants and the \$15.00 warrants, respectively. Total share issuance costs were \$866,612 inclusive of professional fees, the \$136,046 referred to above fees paid to Wainwright, and the fair value of the aforementioned warrants. Issuance costs for the Series B preferred stock are reflected as a reduction of the proceeds from the sale of the preferred stock.

Second Sale of Series B Convertible Preferred Stock: In February 2003, we received gross proceeds of \$2,000,000 from the sale of our Series B convertible preferred stock. We issued to such investors 200 shares of Series B convertible preferred stock, 292,308 shares of common stock (including 92,308 shares of common stock constituting the first year's dividends on such 200 shares of Series B convertible preferred stock, which dividends were paid in advance, and 200,000 shares of common stock, which were issued upon exercise of Series A warrants, exercised at \$.10 per share) and warrants to purchase an additional 200,000 shares of common stock, of which warrants to purchase 100,000 (the B-1 warrants) shares were exercisable at \$15.00 per share and warrants to purchase the other 100,000 (the B-2 warrants) shares were exercisable at \$20.00 per share. In May and June 2003, in conjunction with the conversion of virtually all of the Series B preferred stock and our reverse stock split, these B-1 and B-2 warrants were amended and restated to provide for exercise prices of \$4.00 and \$5.00, respectively. PRF did not convert its 50 shares of Series B preferred stock on May 23, 2003 and, accordingly, the exercise price of its B-1 and B-2 Warrants were not amended and remained at their original exercise price of \$15.00 and \$20.00, respectively.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Wainwright acted as placement agent in this private placement and in addition to cash compensation, we granted warrants to purchase an aggregate of 37,692 shares of common stock, exercisable at \$0.01 per share, to employees of the placement agent firm. The fair value of these warrants was \$86,692. Total share issuance costs were \$393,488 inclusive of professional and investment banking fees and the fair value of the aforementioned warrants. Issuance costs for the Series B preferred stock are reflected as a reduction of the proceeds from the sale of the preferred stock. During 2004 certain of these warrants to purchase 32,460 shares of our common stock were exercised. We received \$325.00.

Dividends were payable in cash or common shares at our option, at the rate of 12% per annum. An accrued dividend of \$50,000 at December 31, 2004 was provided for within stockholders' deficit, as it was our intention to issue common shares in payment of the dividend. These dividends were paid upon the conversion of the Series B preferred on January 5, 2005 as described in Note 10.

Sale of Series C Convertible Preferred Stock: In May and July 2003, we received gross proceeds of \$5,690,000 from the sale of 948 shares of Series C convertible preferred stock, issuing warrants to purchase 1,707,000 shares of our common stock exercisable at \$3.60 per share. Our Series C preferred stock had a stated value of \$6,000 per share and was convertible into 2,844,999 shares of common stock at \$2.00 per share. In addition, in connection with the Series C financing, investors, other than Paul Royalty Fund, agreed to convert their Series B preferred shares into common shares or their equivalent. As a result, 605,389 shares of Series B preferred stock were converted into 2,421,556 shares of common stock and 482,885 shares of Series B preferred stock were converted into an equal number of shares of Series D preferred stock (with a common stock equivalent of 1,931,540 shares). The Series D convertible preferred stock is non-redeemable and has a stated value of \$10,000 per share. As part of the May 2003 Series C financing, employees of the investment-banking firm which arranged the Series C financing were granted warrants to purchase 149,520 shares of our common stock at an exercise price of \$.01 as part of their compensation. Accordingly, we recorded \$269,000 in Series C preferred share issuance costs related to the warrants issued. Total share issuance costs were \$797,327 inclusive of professional and investment banking fees and the fair value of the aforementioned warrants. Issuance costs for the Series C preferred stock are reflected as a reduction of the proceeds from the sale of the preferred stock.

Dividends were payable in cash or common shares at our option, at the rate of 10% per annum. An accrued dividend of \$563,805 and \$336,550 at December 31, 2004 and 2003, respectively, was provided for within stockholders' deficit. In January 2005 we issued common shares in payment of these dividends.

Deemed Dividend: In conjunction with these conversions, all Series B-1 and B-2 warrants were amended to provide for revised exercise prices of \$4.00 and \$5.00, respectively. Paul Royalty Fund did not exercise its right to convert its 50 shares of Series B preferred stock into common stock or its equivalent and as such, its B-1 and B-2 warrants were not amended and remained at their original exercise prices of \$15.00 and \$20.00, respectively. As a result of the change in the B-1 and B-2 warrants at May 23, 2003, we recognized a deemed dividend to investors of \$519,000.

Based on the relative fair market value of the preferred stock at the dates of issuance and the estimated fair market value of the warrants, using the Black-Scholes option pricing model, at December 31, 2003, we assigned values to the Series C preferred stock and the Series C warrants of \$4,464,368 and \$1,225,632, respectively. Similarly, we assigned values to the Series D preferred stock, based on values previously assigned to the Series B preferred stock.

Additionally, since the effective conversion price of the Series C preferred stock on the date of issuance was lower than the market value of the common shares on that date, we recognized \$691,000 of additional discounts on the preferred issuances. This conversion feature was charged to retained earnings as accretion of discount.

In August 2003, holders of 483 shares of Series B convertible preferred stock converted their shares into an equal number of shares of Series D convertible preferred stock.

In June and October 2004, a holder of 35,624 shares of Series C preferred stock with a value of \$137,752, converted its shares into 106,872 shares of common stock. Additionally we issued 13,743 shares of our common stock valued at \$30,099 as payment of dividends on the converted Series C preferred stock.

ORTEC INTERNATIONAL, INC.
(A DEVELOPMENT STAGE ENTERPRISE)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

12 - STOCK OPTIONS

In April 1996, the Board of Directors and stockholders approved the adoption of a stock option plan (the "Plan"). The Plan provided for the grant of options to purchase up to 35,000 shares of our common stock. These options may be granted to employees, our officers, our non-employee directors, consultants, and advisors. The Plan provides for granting of options to purchase our common stock at not less than the fair value of such shares on the date of the grant. Some of the options generally vest ratably over a four-year period, while others vest immediately. The options generally expire after seven years.

In August 1998, the stockholders and Board of Directors ratified and approved an amended and restated 1996 Stock Option Plan increasing the maximum number of shares of our common stock for which stock options may be granted from 35,000 to 155,000 shares. In August 2000, the stockholders and Board of Directors ratified and approved the second amendment to our Amended and Restated 1996 Stock Option Plan increasing the number of shares of our common stock for which options have been or could be granted under the Plan from 155,000 to 300,000 shares.

In February 2003, the stockholders and Board of Directors ratified and approved an amended and restated Stock Option Plan, increasing the maximum number of shares of our common stock for which stock options may be granted from 300,000 to 450,000 shares. As of December 31, 2005, 15,458 options were available for grant under the Plan.

In July 2005, the Board of Directors and stockholders approved the adoption of the 2005 Stock Option Plan (the "2005 Plan"). The 2005 Plan provides for the grant of options to purchase up to 1,000,000 shares of our common stock. These options may be granted to employees, our officers, our non-employee directors, consultants, and advisors. The 2005 Plan provides for granting of options to purchase our common stock at not less than the fair value of such shares on the date of the grant. As of December 31, 2005, all of the 1,000,000 options were available for grant under the 2005 Plan.

Our Board of Directors or its Stock Option Committee has determined the exercise price for all stock options awarded.

ORTEC INTERNATIONAL, INC.
(A DEVELOPMENT STAGE ENTERPRISE)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

The following table summarizes the stock option activity through December 31, 2005:

	Number	Weighted average exercise price (\$)
Granted – adoption of stock option plan	15,600	70.80
Balance, December 31, 1996	15,600	70.80
Granted	12,300	119.40
Forfeited, expired	(300)	66.30
Balance, December 31, 1997	27,600	92.50
Granted	68,975	121.00
Exercised	(675)	74.20
Forfeited, expired	(1,450)	111.90
Balance, December 31, 1998	94,450	111.70
Granted	39,900	108.70
Forfeited, expired	(22,100)	149.30
Balance, December 31, 1999	112,250	103.30
Granted	44,996	79.60
Exercised	(350)	70.00
Forfeited, expired	(4,485)	82.70
Balance, December 31, 2000	152,411	123.00
Granted	75,650	59.30
Forfeited, expired	(24,730)	74.10
Balance, December 31, 2001	203,331	85.40
Granted	115,511	12.90
Forfeited, expired	(31,630)	76.80
Balance, December 31, 2002	287,212	57.30
Granted	160,861	2.20
Forfeited, expired	(99,874)	84.02
Balance, December 31, 2003	348,199	24.16
Granted	129,500	1.92
Forfeited, expired	(49,375)	20.32
Balance, December 31, 2004	428,324	15.40
Granted	36,000	0.33
Forfeited, expired	(29,782)	15.34
Balance, December 31, 2005	434,542	14.16

The following data has been provided for exercisable options:

	Year ended December 31,		
	<u>2005</u>	<u>2004</u>	<u>2003</u>
Number of options	347,267	258,574	250,508
Weighted average exercise price	\$16.92	\$23.04	\$ 29.98
Weighted remaining contractual life	3.59 years	4.18 years	4.79 years

ORTEC INTERNATIONAL, INC.
(A DEVELOPMENT STAGE ENTERPRISE)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

The following table summarizes option data as of December 31, 2005:

Range of exercise prices	Number outstanding	Weighted Average Remaining Contractual Life (years)	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
\$0.26 to \$0.99	64,500	4.40	\$ 0.63	60,000	\$ 0.62
\$1.80 to \$8.75	285,736	4.18	\$ 2.81	204,611	\$ 3.07
\$29.10 to \$80.00	67,630	2.45	\$ 53.88	65,980	\$ 53.74
\$90.00 to \$127.50	<u>16,676</u>	1.81	\$ 99.84	<u>16,676</u>	\$ 99.84
	<u>434,542</u>	3.85	\$ 14.16	<u>347,267</u>	\$ 16.92

We recognized approximately \$1,696,000 of compensation expense for options and warrants issued to officers and our directors in 1998. Such options and warrants were accounted for as variable option grants. Such options and warrants had vested prematurely in December 1998, upon the exercise of warrants owned by one of our directors, in accordance with the terms of certain compensation provisions provided for and approved by our Board of Directors.

During the years ended December 31, 2005, 2003 and 2002, we issued 6,359,238 (see Note 10), 894,400, and 380,000 options, respectively, to senior executives, which were not included in the Plan. During the year ended December 31, 2004 we issued 100,000 options to a director which was not included in the Plan. These options vested immediately and expire seven years from date of grant. The following table provides the exercise price for options issued to the director and senior management.

Number Outstanding	Exercise Price	Remaining Contractual Life (years)
6,359,238	\$ 0.25	6.81
460,000	\$ 1.80	4.15
140,000	\$ 2.00	3.96
74,000	\$ 2.10	4.42
380,000	\$ 3.50	3.89
320,400	\$ 3.60	4.18
<u>7,733,638</u>		

In addition, we recognized \$7,189 and \$94,393 in consulting expense in 2005 and 2004, respectively, for warrants granted to independent consultants for services rendered to us.

13 - RELATED PARTY TRANSACTIONS

Due to Founder

Pursuant to an amended agreement, we had engaged the services of Dr. Mark Eisenberg, one of our directors, who is also one of our founders, as a consultant through August 31, 2005. During 2003, we terminated our agreement with Dr. Eisenberg and discontinued research activities in Australia. For the period from inception to December 31, 2003 production and laboratory costs include compensation due to Dr. Eisenberg of approximately \$1,029,000. In accordance with the settlement agreement, we recorded consulting expense of \$194,656 for the remainder of the \$304,478 of consulting fees due under the consulting agreement with Dr. Eisenberg. Additionally, we recorded \$28,881 in rent expense that we owed Dr. Eisenberg for the space we occupied in the Australian laboratory. The total amount due Dr. Eisenberg under the settlement agreement aggregated \$398,574 which represents unpaid consulting fees, the rent for the Australian laboratory, and \$65,215 of advances made by Dr. Eisenberg on our behalf. We settled the balance due Dr. Eisenberg in 2004 by issuing 100,000 options to purchase our common stock at an exercise price of \$2.00 per share. We recorded the \$398,574 settlement in 2004 as a contribution of capital given that the settlement was with our director. These options will expire in five years.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Research Collaboration

On October 11, 2004 we entered into a collaboration with Hapto Biotech, Inc., for the purpose of further developing promising product leads identified through a research collaboration established in September 2002 between us and Hapto Biotech, utilizing each company's proprietary technologies. The activities of the two entities has been conducted in a new entity, Hapto / Ortec Collaboration, LLC. The agreement provides for a license agreement to us if the collaboration is successful in developing other technology (as defined) which can be used to treat hard to heal chronic wounds (as defined). See "Letter of Intent" in Note 14.

Change of Control Agreements

In December 1998, our Board of Directors authorized agreements between us and two of our executive officers and another employee, which state that in the event of a "change of control" certain "special compensation arrangements" will occur. A "change of control" is defined as a change in the ownership or effective control of Ortec or in the ownership of a substantial portion of our assets, but in any event if certain members of our Board of Directors no longer constitute a majority of the Board of Directors. In the event that such change of control occurs, the agreements provide these individuals additional compensation, interest-free loans to exercise their stock options and warrants, and extensions of the expiration dates of all of their then outstanding options and warrants so that none will expire in less than three years from such termination of employment. In addition, for all of the individuals, in the event of a change of control, all unvested options and warrants will vest immediately upon such change of control.

14 - COMMITMENTS AND CONTINGENCIES

Cell Therapy Manufacturing Agreement

In October 29, 2003 we entered into an agreement commencing November 1, 2003 with Cambrex Bio Science Walkersville, Inc., a subsidiary of Cambrex Corporation (Cambrex), for Cambrex to manufacture ORCEL in Cambrex's Walkersville, Maryland facilities. The Cambrex manufacturing facility is required to meet FDA's good manufacturing processes standards. Cambrex is experienced in the manufacture of cell-based medical products such as our ORCEL.

Our agreement with Cambrex requires us to currently pay Cambrex \$132,613 per month, or \$1,591,350 per year, for the use of a production suite in their facility located in Walkersville, Maryland. The payments we will make to Cambrex will increase to \$175,000 monthly, or \$2,100,000 per year, if we require Cambrex to build us a larger production facility to meet our requirements for the production of ORCEL. In 2005 and 2004 we incurred charges of \$1,552,725 and \$1,332,500, respectively, for the use of Cambrex's production facility. These amounts are included in product and laboratory costs. Such annual payments include some services and overhead expenses provided and paid for by Cambrex. These annual payments we are required to make increase 3% per annum on the anniversary of the commencement date. We are required to pay 50% of the cost of the construction of that larger production facility up to \$1,000,000 (up to \$2,500,000 if we terminate our Sales Agency Agreement with Cambrex). However, the amount we contribute to the construction of that larger facility will be repaid to us by credits against a portion of the future annual payments of \$2,100,000 and of certain other payments we are required to make to Cambrex after the larger facility is in use. We are also required to pay specified hourly charges for the Cambrex employees engaged in the production of ORCEL as well as certain other charges. After construction of the larger production facility we are required to acquire from Cambrex virtually all of our requirements for ORCEL that Cambrex can produce. Prior to our election to have Cambrex construct the larger production facility for us, either we or Cambrex may terminate the agreement on six months notice by us and twelve months notice by Cambrex. If we elect to have Cambrex construct the larger production facility for us the agreement will continue for six years after the larger production facility is constructed. However, even after such construction we and Cambrex may elect to scale down over the following three years the portion of our requirements for ORCEL that Cambrex will produce for us. We may elect the scale down period at any time after one year after the larger production facility is constructed and in operation in which event there are additional payments we must make to Cambrex. If we elect the scale down period after one year we must pay Cambrex \$2,625,000 and if we elect the scale down period after two years we must pay Cambrex \$1,050,000. If we elect the scale down periods in either of those two years, we forfeit our right to receive any further credits (up to the amount of our contribution to the cost of the larger production facility) against payments we are thereafter required to make to Cambrex. Either Cambrex or we may elect the scale down period later than three years after that facility is in operation and neither of us will be required to make any additional payments to the other because of that election. If after the construction

ORTEC INTERNATIONAL, INC.
(A DEVELOPMENT STAGE ENTERPRISE)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

of the larger production facility we breach a material term of our agreement with Cambrex, or elect to terminate the agreement, we will have to pay Cambrex the following amounts:

<u>If termination occurs after the following anniversary of the construction of the larger production facility</u>	<u>Amount of Payment</u>
6 years	\$1,050,000
5 years, but less than 6 years	1,575,000
4 years, but less than 5 years	2,625,000
3 years, but less than 4 years	3,675,000
2 years, but less than 3 years	5,250,000
1 year, but less than 2 years	6,300,000

In addition, upon such termination we will forfeit our right to receive any further credits (up to the amount of our contribution to the cost of the larger production facility) against future payments we may have to make to Cambrex.

Sales & Marketing Agreements

License Agreement: In October 2003, we entered into an exclusive License Agreement with Teva Medical Limited, a subsidiary of Teva Pharmaceutical Industries Ltd. (Teva) for the sales and marketing of our ORCEL product in Israel. This ten-year agreement, beginning on the date the product is launched for marketing in Israel, requires Teva to seek regulatory and reimbursement approval for ORCEL in Israel. We received an upfront payment of \$50,000 in 2003 which we recorded as deferred income, see Note 6. We will receive an additional \$50,000 within thirty days of grant of reimbursement approval in Israel, and another \$100,000 within 30 days of attainment of aggregate net sales of \$3,000,000 in Israel within any period of twelve consecutive calendar months. The agreement also provides for ORCEL pricing and terms of payment. Additionally Teva will pay us royalties of 10% of net sales in Israel up to \$5,000,000 per annum. If sales are in excess of \$5,000,000 annually Teva will pay us 10% on the first \$5,000,000 of sales in Israel and a 20% royalty on sales above \$5,000,000 in Israel. As of December 31, 2005, regulatory and reimbursement approval have not been achieved.

Sales Agency Agreement: On October 18, 2004 we entered into a Sales Agency Agreement with Cambrex, providing for Cambrex to be the exclusive sales agent in the United States for our ORCEL product or any other future bi-layered cellular matrix product of ours for the treatment of venous stasis ulcers, diabetic foot ulcers or any other therapeutic indication for dermatological chronic or acute wound healing. The agreement is for a period of six years beginning sixty days after we receive clearance from the FDA for the commercial sale of our ORCEL for the treatment of venous stasis ulcers. The agreement requires us to pay commissions to Cambrex ranging from initially at 40% of net sales and decreasing to 27% of net sales as the amount of sales increases. The agreement requires Cambrex to spend \$4,000,000 for marketing efforts during the sixteen-month period after the FDA clears our sale of ORCEL for the treatment of venous stasis ulcers.

Cambrex had the right to terminate the agreement if we did not receive FDA clearance for commercial sale of ORCEL for the treatment of venous stasis ulcers by April 1, 2005, and has the right to terminate if for any period of six consecutive months beginning in 2007, sales are less than 9,000 units. We may terminate the agreement if sales of ORCEL are less in any twelve month period than amounts targeted in the agreement for that period (ranging from 10,000 units in the first twelve month period to 100,000 units in the sixth twelve month period).

Concurrent with the Sales Agency Agreement we entered into a License Agreement pursuant to which we licensed certain intellectual property rights to Cambrex. We also entered into a Security Agreement with Cambrex to secure the performance of our obligations under the Manufacturing, License, and Sales Agreement. The secured collateral consists of all accounts, cash, contract rights, payment intangibles, and general intangibles arising out of or in connection with the sale of products pursuant to the sales agreement and/or license agreement, and all supporting obligations, guarantees and other security therefore, whether secured or unsecured, whether now existing or hereafter created. The lien and security interest under this security agreement is subordinate and junior in priority to the perfected lien and security interest granted to Paul Royalty Fund as secured party under the Paul Royalty Security Agreement.

In connection with the Sales Agency Agreement, our manufacturing agreement with Cambrex was modified so that if Cambrex builds us a larger production facility the maximum amount we could be required to contribute to that construction was reduced from \$2,500,000 to \$1,000,000.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Supply Agreements

Cell supply agreement: In April 2004, we entered into a Material Supply Agreement with ES Cell International Pte Ltd.(ESI). Under the terms of the agreement, we provided ESI with human skin cells generated from cell lines developed and manufactured by us for use in our ORCEL product. We received a \$50,000 up-front fee upon the signing of the agreement and we received an additional \$150,000 upon first delivery of certain specified cell lines. We have recorded these amounts in interest and other income in 2004. We will receive milestone payments of \$150,000 within 30 days of an investigational new drug filing for the ESI Focus Cell Therapy line and an additional \$150,000 upon ESI's receiving regulatory approval for marketing of the ESI Focus Cell Therapy product. We will additionally receive royalties equivalent to .5% of product sales revenue or license or distribution fees or other payments. The payment of these additional amounts are wholly dependent on ESI achieving their milestones. No additional payments were received in 2005.

Sponge supplier: We purchase bovine collagen sponges, a key component of ORCEL, from one supplier who produces the sponges to our specifications. On December 30, 2004 we entered into a two-year supply agreement with this supplier. Under such agreement we agreed to minimum purchase commitments. We agreed to purchase a minimum of 3,500 units of finished collagen sponges within the first twelve-month period. The value of such commitment is approximately \$200,000. Such commitment was not achieved in 2005 and we were released from any resulting liability by the supplier. We also agreed that subsequent to a written notification from the FDA allowing us to sell ORCEL commercially for treatment of venous stasis ulcers we will provide such supplier projections for one or more subsequent quarters and the parties will be obligated to purchase and sell those projected amounts.

Government Regulation

We are subject to extensive government regulation. Products for human treatment are subject to rigorous preclinical and clinical testing procedures as a condition for clearance by the FDA and approval by similar authorities in foreign countries prior to commercial sale. Presently, we are continuing our clinical trials for the use of our product in the treatment of patients with venous stasis ulcers and to submit the results of our human clinical trials to the FDA; however, it is not possible for us to determine whether the results achieved from the human clinical trials will be sufficient to obtain FDA approval. If we are unable to obtain FDA approval, we may no longer be able to continue our operations. It is not possible for us to determine whether the results achieved from that human clinical trial will be sufficient to obtain FDA clearance.

Letter of Intent

In December 2005 we executed a non-binding letter of intent to acquire Hapto Biotech (Hapto), a privately-held company focused on the development of two proprietary fibrin derived platform technologies: Fibrin Micro Beads (FMB's) and Fibrin based peptides, (Haptides™). Hapto's research indicates that FMB's have the ability to optimize the recovery, potential delivery and therapeutic value of adult stem cells. In October 2004, Ortec and Hapto initiated their relationship by forming a joint venture to combine our proprietary collagen biomaterial technology and Hapto's Haptide™ peptide technology to develop non cellular, biologically active enhanced biomaterials to promote the attraction and attachment of cells for application to the wound healing, reconstructive, cosmetic, tissue regeneration and dental markets. We closed our acquisition of Hapto on April 14, 2006. For such acquisition we issued a total of 30,860,000 shares of our common stock to the Hapto shareholders and granted them warrants to purchase an additional 3,000,000 of our common shares at \$0.30 per share. The investment banking firm of Rodman & Renshaw, LLC acted as our advisor in this acquisition.

15 - INCOME TAXES

We have deferred start-up costs for income tax purposes and intend to elect to amortize such costs over a period of 60 months, under Section 195(b) of the Internal Revenue Code, when we commence operations.

At December 31, 2005, we had net operating loss carry-forwards of approximately \$30,781,000 for Federal and New York State income tax purposes expiring through 2025. Due to the merger of Skin Group with and into Ortec in July 1992, the net operating losses and other built-in deductions existing at that time were subject to annual limitations pursuant to Internal Revenue Code Section 382. Our ability to utilize net operating losses and other built-in deductions generated after that date may be limited in the future due to additional issuances of our common stock or other changes in control, as defined in the Internal Revenue Code and related regulations.

ORTEC INTERNATIONAL, INC.
(A DEVELOPMENT STAGE ENTERPRISE)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

For financial statement purposes, a valuation allowance of approximately \$56,795,000 at December 31, 2005 has been recognized to offset entirely our deferred tax assets, which arose primarily from our operating loss carry-forwards and the deferral of start-up expenses for tax purposes, as the realization of such deferred tax assets is uncertain. Components of our deferred tax asset are as follows:

Net operating loss carry-forwards	\$ 12,928,000
Deferral of start-up costs	29,387,000
Interest	8,381,000
Loss on settlement of promissory notes	5,494,000
Other	605,000
	<u>56,795,000</u>
Valuation allowance	(56,795,000)
Net deferred tax asset	<u>\$ -</u>

The following reconciles the income taxes computed at the federal statutory rate to the amounts recorded in our statement of operations:

	Year ended December 31,		Cumulative from March 12, 1991 (inception) to December 31, 2005
	2005	2004	2005
Income tax benefit at the Statutory rate	\$ (10,327,000)	\$ (5,233,000)	\$ (48,400,000)
State and local income taxes, net of Federal benefit	(2,429,000)	(1,231,000)	(9,563,000)
Permanent difference	8,000	5,000	1,168,000
Effect of valuation allowance	12,748,000	6,459,000	56,795,000
	<u>\$ -</u>	<u>\$ -</u>	<u>\$ -</u>

Our net operating loss tax carry-forwards expire as follows:

Year ending December 31,	
2006	\$ 76,000
2007	233,000
2008	511,000
2009	597,000
2010	440,000
2011	677,000
2012	839,000
2018	1,189,000
2019	2,602,000
2020	3,535,000
2021	4,014,000
2022	3,311,000
2023	3,054,000
2024	5,448,000
2025	4,255,000
	<u>\$ 30,781,000</u>

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

16 - FAIR VALUE OF FINANCIAL INSTRUMENTS

Statement of Financial Accounting Standards No. 107, "Fair Value of Financial Instruments," requires disclosure of the estimated fair value of an entity's financial instrument assets and liabilities. For us, financial instruments consist principally of cash and cash equivalents, loans payable and other long-term obligations.

The following methods and assumptions were used to estimate the fair value of each class of financial instrument for which it is practicable to estimate that value.

Cash and Cash Equivalents

The carrying value reasonably approximates fair value because of the short-term maturity of those instruments.

Loans Payable and Other Long-term Obligations

Based on borrowing rates currently available to us for other financings with similar terms and maturities, the carrying value of our loans payable, capital lease obligations and other long-term obligations approximate the fair value.

17 - RETIREMENT PLAN

The Company maintains a defined contribution 401(k) savings plan (401(k) plan) for the benefit of eligible employees. Under the 401(k) plan, a participant may elect to defer a portion of annual compensation. Contributions to the 401(k) plan are immediately vested in plan participants' accounts. Plan expenses were \$4,485 and \$3,255 for the years ended December 31, 2005 and 2004, respectively. We do not match employee contributions.

18 - SUBSEQUENT EVENTS

Legal Challenge Withdrawn: In January 2006 we were informed that Advanced Tissue Sciences withdrew its appeal against the grant of our European patent of ORCEL. We were originally granted its European patent in December 1997 and received notification in November 1998 that it was being challenged by Advanced Tissue Sciences. In March 2002, we announced that we had successfully defended Advanced Tissue Sciences' opposition filed with the European Patent office and, subsequently, Advanced Tissue Sciences appealed the patent offices' decision, but is now withdrawing that appeal. Withdrawal of the appeal by Advanced Tissue Sciences concludes this litigation and our European patent remains as originally issued.

Modification of Registration Rights Agreement. In October 2005 we closed a private placement in which we sold our common stock and Series F warrants to a group of accredited investors. In connection with such sales we entered into an agreement with such investors whereby we undertook to register all of the shares of our common stock they purchased, and the shares of our common stock issuable upon exercise of our Series F warrants they acquired, in that private placement. We agreed that if we did not file that registration statement by January 6, 2006, or have that registration statement declared effective by March 14, 2006, we would pay liquidated damages to the purchasers. Our agreement with those purchasers provided that the holders of a majority of the shares of our common stock we were required to register pursuant to that agreement (the "majority holders") could modify and/or waive our obligations under that agreement and such modification and/or waiver would be binding on all the purchasers in that private placement. On January 30, 2006 the majority holders (i) waived our obligation to pay any liquidated damages for our failure to file the registration statement by January 6, 2006; (ii) extended to June 7, 2006 the time by which the registration statement had to be declared effective before we had to pay any liquidated damages and (iii) permitted us to include in such registration statement shares of our common stock we may issue, or that will be issuable, in (x) a transaction in which we acquire by merger another biotechnology company and/or (y) a new private placement of our securities in which we raise up to \$10,000,000. Such modification and waiver will enable us to pursue such acquisition and private placement without incurring those liquidated damages expenses.

Availability of Authorized Shares. On January 30 and 31, 2006, North Sound Capital, LLC (North Sound) and SDS Capital Group SPC, Ltd. (SDS) entered into agreements with us whereby they agreed not to convert any of the aggregate of 6,272,0156 shares of our Series D Convertible Preferred Stock owned by them, nor exercise any of our Series F warrants held by them, until such time that we are able to obtain approval from our stockholders to amend our certificate of incorporation to increase the number of shares of our common stock we are authorized to issue, or take such other corporate

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

action, which will enable us to have sufficient number of shares of our common stock which we are authorized to issue, to issue in a private placement of our securities and in the acquisition of a biotechnology company, which proposed transactions are both referred to above. These agreements will provide us with the ability to use the approximately 33,000,000 shares which North Sound and SDS have agreed not to acquire, together with our available authorized shares, in such proposed private placement and acquisition transactions. These agreements will be voided if we are unable to complete the proposed private placement of our securities before April 30, 2006. We have agreed that after the completion of the proposed private placement and/or acquisition we will proceed promptly to file a proxy statement for a meeting of our stockholders at which we expect to increase the number of shares of our common stock we are authorized to issue, or take such other corporate action, to have available for issuance enough shares of our common stock upon conversion of North Sound's and SDS's Series D Convertible Preferred Stock and upon exercise of their warrants.

Reduction of Liquidation Preference. All of the 6,272.0156 shares of our outstanding Series D Convertible Preferred Stock are owned by North Sound and SDS. On January 30 and 31, 2006 North Sound and SDS entered into agreements with us agreeing to exchange all of their shares of our Series D Convertible Preferred Stock into an equal number of shares of our new Series D-1 Convertible Preferred Stock. The only difference between our Series D Preferred shares and our Series D-1 Preferred shares is that the liquidation preference of the Series D Preferred shares is \$10,000 per share and that of the Series D-1 Preferred shares is \$10 per share. Each Series D-1 Preferred share will be convertible (as is each Series D Preferred share) into 4,000 shares of our common stock.

Other than North Sound and SDS, and other of our shareholders and warrant holders who signed the modification and waiver agreements referred to above, being owners of our common stock, of our Series D Convertible Preferred Stock and of our warrants to purchase shares of our common stock, we have no material relationship with any such person.

Cambrex Suite Deal II: On February 13, 2006 we entered into an agreement with our manufacturing and marketing partner, Cambrex, whereby for the six-month period January 1 to June 30, 2006 the \$132,612 monthly charges we incur for rental of a production suite used to produce ORCEL at their Maryland facility, Cambrex has agreed to accept 736,733 shares of our common stock monthly in lieu of a cash payment. During the term of the agreement we will issue an aggregate 4,420,398 common shares for the aggregate amount of \$795,672. We will also issue a three-year warrant commencing July 1, 2006 to purchase 1,105,100 shares of our common stock at \$0.75 per share. Each of these securities will carry certain registration rights.

Third Amendment of Lease: On March 16, 2006 we agreed to a two-year lease extension at our 14,320 square foot New York City lab and office facility location commencing January 1, 2006. We agreed to a monthly rental of \$60,860 or \$730,320 per annum. We will have the option to renew for an additional two years at the rate of \$63,843 per month, or \$766,120 annually.

Vendor Settlement: On March 17, 2006, we settled a vendor liability of approximately \$102,000 for \$35,000 cash payable in seven equal monthly installments and a three-year warrant to purchase 285,000 shares of our common stock at an exercise price of \$0.25. The warrant has piggyback registration rights.

Bridge Financing: In March 2006, we received \$380,000 in short-term loans from two entities. One loan for \$130,000 was from one of our executive officers, is non-interest bearing and is payable from the proceeds of the recent private placement of our securities. The second loan for \$250,000 bears interest at 8% per annum and was from the investor who had a committed to provide us with \$1,058,000 by the later of the filing of our pre-market approval application for our confirmatory venous leg ulcer trial, or March 31, 2006. This \$250,000 loan automatically converted into the equity securities we issued in our recent private placement at 1.2 times the principle and accrued interest amount. Additionally we agreed that since the investor provided us with the funds earlier than was required, upon conversion of such \$250,000 loan to our equity securities, we would forego such investor's \$808,000 remaining commitment and that the earlier repricing (upon commitment) of our warrants held by such investor would not be affected.

On March 31, 2006, we received \$65,000 in a short-term loan from our executive officers, of which \$35,000 was repaid on April 6, 2006. On April 3, 2006 we received another short-term loan of \$45,000 from another of our executive officers. Both of these loans will be repaid from the proceeds of our recent private placement. On April 17, 2006, with the completion of our recent private placement, we converted the \$250,000 short-term loan with its then outstanding loan balance of \$301,333 into 301.33 shares of Series E Preferred Stock, and issued a warrant to purchase 1,506,665 shares of our common stock at an exercise price of \$0.50 per share. On April 5, 2006 we received a \$200,000 a short-term loan due

ORTEC INTERNATIONAL, INC.
(A DEVELOPMENT STAGE ENTERPRISE)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

April 30, 2006 to be repaid at 110% of principal plus accrued interest at 8% per annum on the original \$200,000 principal balance. We issued a three-year warrant to purchase 50,000 shares of our common stock at an exercise price of \$0.50 per share to the lender.

Private Placement: On April 17, 2006, we completed a private placement sale for aggregate gross proceeds of \$6,176,000 to accredited investors of our 6% Series E Convertible Preferred Stock and warrants to purchase our common stock. The Series E Convertible Preferred Stock is entitled to vote on an "as converted" basis on all matters submitted to a vote by the holders of the common stock. At any time these investors can convert their preferred stock into common stock at a \$0.20 conversion price. If we complete a reverse split of our outstanding common stock by June 16, 2006, the investors are obligated to convert their preferred stock on the 21st trading day following such reverse split by dividing the amount they paid for such preferred shares plus dividends at 6% per annum, by the lesser of \$0.20, or 90% of the average of the volume weighted average prices for our common stock for the twenty trading days following the effective date of such reverse stock split. We issued five-year warrants to purchase our common stock at \$0.50 per share, for the number of common shares equal to the purchase price paid for our convertible preferred shares divided by \$0.20, or warrants to purchase an aggregate of 30,880,000 of our common shares. The warrants carry full ratchet price reset provisions should we sell our common stock or our other securities convertible into, or exercisable for, our common stock, at an effective price per common share less than the \$0.50 exercise price of the warrants. We are obligated to register, under the Securities Act of 1933, all of the shares of our common stock issuable upon conversion of the 6% Series E Convertible Preferred Stock, or upon exercise of such warrants. We will pay investors 2% per month for any failure to timely file by June 18, 2006 or obtain an effective registration statement by August 17, 2006.